upon not only his or her own skills, but also would have taken advantage of certain specialized skills of others on the team when solving a technical problem."

## VII. U.S. PATENT NO. 9,480,836

### A. Direct Infringement

#### 1. Legal Standard: Literal Infringement[25]

"Determination of infringement is a two-step process which consists of determining the scope of the asserted claim (claim construction) and then comparing the accused product . . . to the claim as construed." *Certain Sucralose, Sweeteners Containing Sucralose, and Related Intermediate Compounds Thereof*, Inv. No. 337-TA-604, Comm'n Opinion at 36 (U.S.I.T.C., April 28, 2009) (citing *Litton Sys., Inc. v. Honeywell, Inc.*, 140 F.3d 1449, 1454 (Fed. Cir. 1998)).

An accused device literally infringes a patent claim if it contains each limitation recited in the claim exactly. *Litton*, 140 F.3d at 1454. Each patent claim element or limitation is considered material and essential. *London v. Carson Pirie Scott & Co.*, 946 F.2d 1534, 1538 (Fed. Cir. 1991). In a Section 337 investigation, the complainant bears the burden of proving infringement of the asserted patent claims by a preponderance of the evidence. *Enercon GmbH v. Int'l Trade Comm'n,* 151 F.3d 1376, 1384 (Fed. Cir. 1998). If any claim limitation is absent, there is no literal infringement of that claim as a matter of law. *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1247 (Fed. Cir. 2000).

#### 2. FDA Overview

As an initial matter, Serendia's expert, Mr. Crosby, explained in detail the steps ("Steps

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[25] Serendia did not assert infringement against any of the Asserted Patent under the doctrine of equivalents.

1-5") of the U.S. Food and Drug Administration's ("FDA") 510(k) clearance process under the Food, Drug and Cosmetic Act. Title 21 U.S.C. § 800 et seq. requires device manufactures, who must register depending upon the program and device, to notify the FDA of their intent to market a medical device at least 90 days in advance.[26] The FDA 510(k) clearance process was required for the devices at issue in this Investigation, which Respondents' experts did not dispute or rebut. The FDA 510(k) clearance process is extensive and complicated. *See* 21 C.F.R. § 807. It involves a comprehensive review of safety and performance data for a given device, which may include submission of designs and labeling and various type of scientific evidence such as clinical tests and/or trials. A 510(k) premarket submission must demonstrate to the FDA that the device to be marketed is safe and effective. Mr. Crosby also described at length his own experience with such clearances, which, again, Respondents' experts did not contest or rebut.

As discussed below, Respondents made ***unequivocal*** representations to the FDA in their 510(k) submissions which demonstrate, again ***unequivocally***, that the Accused Products practice the asserted claims of the '836 patent, namely, the coagulation limitation recited in independent claims 1 (asserted) and 14 (not asserted), from which asserted claims 9 and 22 depend, and which Respondents hotly disputed.[27] Specifically, in [redacted]

[26] The FDA's 510(k) product pre-clearance guidance required submissions, classification of products, and the FDA review process are described in detail on the FDA website. In addition to the testimony that was provided by witnesses during this Investigation, and the documents that the Parties submitted with respect to their own 510(k) product pre-clearance submissions to the FDA (which included detailed descriptions on clinical testing) with FDA responses thereto, judicial notice is taken here under FRE 602 of the FDA's guidance and information on the 510(k) submission and review process that is contained on the FDA website at https://wwwfda.gov. (*See also* CX-1071 (FDA Premarket Notification 510(k) Guidance).). Microneedling is specifically described in Title 21 CFR 878.4430.

[27] Claim 9 depends from claim 1, which is an apparatus claim. (JX-0007 at cls. 1, 9.). Claim 22 depends from claim 14, a method claim which corresponds to claim 1. (*Id.* at cls. 14, 22.).

[redacted] (CX-0166C (Potenza 510(k)) at 22 [redacted] (emphases added); CX-0339C (Intensif 510(k)) at 23 [redacted] (emphases added).).

For the following reasons, which elaborate on the points made above, Respondents' feeble and un-creditable attempts to discredit the explicit language of the ***certified*** representations they themselves made to the FDA in their 510(k) submissions, to advance their non-infringement arguments in this Investigation, have been found to be neither credible nor persuasive, not to mention disingenuous and potentially ethically questionable.

**a) FDA 510(k) Clearance Process**

During the Hearing, Mr. Crosby provided the following description of Steps 1-5 of the FDA 510(k) pre-clearance process for electrosurgical medical devices. Mr. Crosby summarized these steps in his demonstratives, which are replicated below in Figures 7 and 8.

Q. I'd like to move on to another topic and ask you a few questions about the FDA clearance process. I am on slide 110 now.

Can you tell us, at a high level, what does the device development process look like for the FDA?

A. The device development process is governed by Title 21 of the Code of Federal Regulations, which is a lot of language. The FDA helpfully publishes their summary of the device development process on their webpage. And they describe it as having five steps, listed here.

Q. What are they?

A. Step 1 is device discovery and concept, which is research and development for

new device, which begins in the laboratory.

Step 2 is preclinical research usually on a prototype device, where we would subject the device to laboratory testing and engineering testing, perhaps animal, testing to answer basic questions about safety.

Once we have adequate information, we would then do some sort of human testing to make sure they are safe and effective under pathway to clearance step 3. All of that information is assembled and submitted to the Food and Drug Administration for review.

The FDA review teams in step 4 thoroughly examine all that submitted data and make a decision whether or not to provide clearance.

And after the FDA provides clearance to market, the sponsor, the company, has an obligation to comply with the FDA mandated postmarket safety monitoring requirements.

Q. For products that have already been approved but sponsor company is seeking a new indication, what steps would they have to go through for that approval process for the new indication?

A. At least steps 3, 4, and 5. If the new indication requires a modification, perhaps some of the other ones too.

Q. Are these steps regulated by the FDA?

A. They are indeed. The FDA regulates, not only what you have to do, which is listed in this process here, but how you have to do it and who has to do it.

Q. In terms of the who, who is generally involved in the clearance process for devices like the products that we have been discussing in this investigation?

A. The who includes at least the members of the company, the clinical trials people, the R&D people, the quality assurance people. There are often external consultant, there may be regulatory consultants. There may be clinical time frame consultants. There may be engineering consultants. Companies often rely on information and opinions from medical practitioners. They are usually referred to as key opinion leaders. Sometimes they are assembled into a medical advisory board. So the sponsor will utilize multiple external and internal people to support their 510(k) application.

Q. In your experience, is this an involved and expensive process?

A. I've yet to meet to a doctor who works for nothing, so this is very expensive process, yes.

Q. Focusing on step 5 of the device development process, what are some of the activities that companies have to engage in to meet that step?

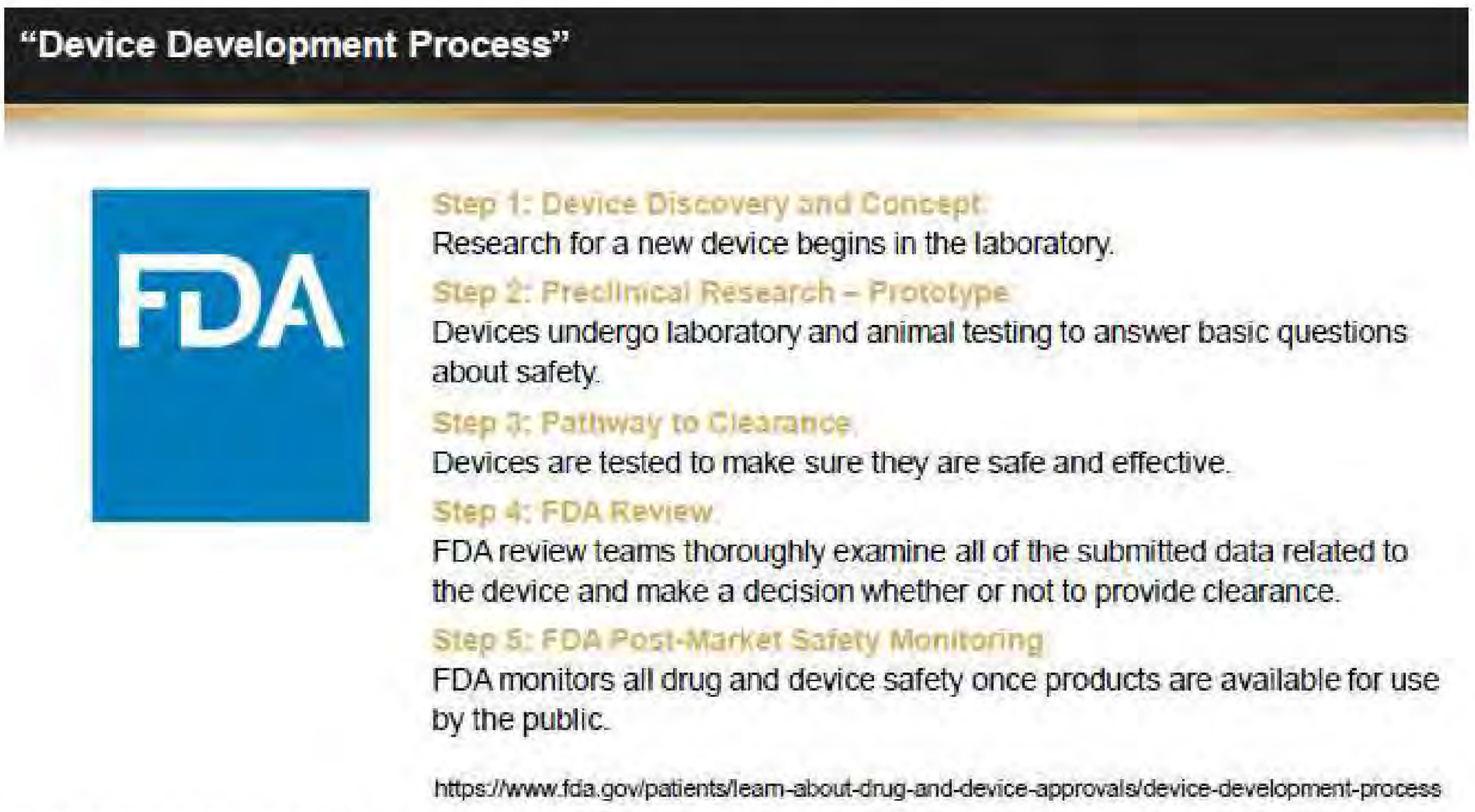
A. The fundamental question here to be answered is, does the real-world performance of a device cleared for market match the performance of the controlled environment of the clinical trial. So monitoring real world performance is one of the key obligations of the sponsor.

And that involves reviewing and responding to complaints and feedback from the field. If there are issues, they need to be reported through the medical device reporting system maintained by the FDA.

The company is required to train users to use their device. You wouldn't want to fly in a plane when the pilot announced it was his first flight. It is necessary to maintain an adequate supply chain and distribution management so you know where your products are, and that they are delivered in a safe manner and installed correctly. And, finally, it's absolutely crucial to maintain traceability. It is an obligation of the sponsor to know where every single product is at every time.

(Tr. (Crosby) at 638:21-641:24.).

**Figure 7: Crosby Demonstrative Listing Steps of FDA Device Development Process**




(CDX-0001C.0110 (citing FDA web page).).[28]

[28] The contents of CDX-0001C.0110 copy verbatim Steps 5 identified in the cited FDA web page.

**Figure 8: Crosby Demonstrative Elaborating on Step 5**




(CDX-0001C.0111.).

Mr. Crosby also explained at length his experience with seeking FDA 510(k) clearance for such medical devices.

> Q. . . . [C]an you please describe or highlight an experience or two of yours in which you were involved in seeking FDA 510(k) clearance for a medical device?
>
> A. Sure. At NeoVision, which was a device for three dimensional ultrasound imaging of breasts to enable fine needle biopsy, I collected all the engineering drawings and assembled them. I collected the -- well, we conducted some human clinical trials, and I recorded and collected the data from that.
>
> I assembled the entire collection of information, including additional information about our quality system and submitted it to the FDA and interacted with the FDA until we got 510(k) clearance.
>
> Would you like another example?
>
> Q. One more would be great. Thank you.
>
> A. Sure. So in Ischemia Technology, which is an in vitro diagnosis device, also subject to the 510(k) regulations, we put together the dossier of information, which is probably about a thousand pages, of the way the device is designed, the way it works, the way it's manufactured, the way quality is assured, which is the engineering technical background.
>
> We put together information from a clinical trial that I designed and ran from

multiple patients. We put together information about how the product would be manufactured and the quality of that manufacturing would be maintained, and we submitted that to the FDA.

Ironically, in this case, the FDA changed their mind and said they wanted a PMA, so we had to pivot and redo it as a PMA application, which I did personally. I submitted the first two of three modules of the PMA, and then the FDA changed their mind again and said that it's okay to be a 510(k). So I resubmitted the 510(k), and we eventually got 510(k) clearance.

Q. You used --

JUDGE MCNAMARA: Pardon me. What is the PMA?

THE WITNESS: I beg your pardon?

JUDGE MCNAMARA: Could you define PMA, please?

A. Yes. I beg your pardon. The FDA classifies device according to their risk. PMA stands for premarket approval, and that's a pathway to market, which requires FDA to evaluate the safety and efficacy of a product as opposed to what's called the 510(k) process, which requires the FDA to evaluate substantial equivalence to a product that's already marketed.

Q. Are you familiar with clinical trial protocols for medical devices?

A. Yes. I'm familiar with clinical trial protocols. I've authored multiple clinical trials. I even have a patent on how to run a clinical trial.

Q. What goes into putting together a clinical trial protocol?

A. Are you asking what is my personal experience, how many have I done?

Q. I'm asking, based on your personal experience, what goes into writing a clinical trial protocol?

A. A clinical trial protocol usually involves consultation with multiple external parties, usually potential customers, key opinion leaders, perhaps a medical advisory board. It often involves consultation with regulatory consultants, either external or internal, to figure out the regulatory pathway to market. It often involves consultation with biostatisticians to figure out the numbers required for the clinical trial to prove the hypothesis one way or another.

It involves interacting with an Institutional Review Board or IRB, sometimes called an ethics committee, to get permission to collect data on human patients and perform procedures on human patients. It involves training the people who will be conducting the clinical trial. It involves negotiating clinical trial contracts with

each of the parties. Often the institution and the investigator have separate contracts.

So a clinical trial would involve, say, ten investigators at ten sites will involve 20 contracts. And then to conduct a clinical trial involves following the training and repeat training to ensure the trial is done properly, sending representatives to the clinical trial site to make sure the trial is conducted properly, and then monitoring the data to ensure that it meets the clinical trial requirements.

Q. In your experience in preparing 510(k) submissions for medical devices, did you consult any materials published or provided by the FDA for that process?

A. Some of the material is published by the FDA, if I understand your question correctly. Most of the material submitted by the company to the FDA remains company confidential.

Is that what you're asking?

Q. A slightly different question. My question goes to preparing the materials for submission to the FDA.

A. Yes.

Q. Does the FDA provide any guidance or materials publicly at companies that you've consulted in preparing those submissions?

A. I see. I misunderstood the question. Sorry.

Yes, the FDA publishes multiple guidance documents in multiple fields. There are thousands out there. And it's important to follow the guidance in the documents if you want to get your product cleared.

Q. Why is it important?

A. Because if you don't follow the guidance, the FDA is unlikely to clear it.

Q. I believe you talked about the FDA device development process, the five steps that the FDA provides summarizing that process.

Do you recall that?

A. I do.

Q. In your experience seeking FDA approval for medical devices, did you follow each of the five steps that the FDA publishes for that process?

A. Yes, I did.

Q. Why?

A. Well, the Code of Federal Regulations that governs the FDA mandates certain numbers of these steps to be done, and the guidance that the FDA publishes on their webpages, as I showed in my slide, is a high level list of the steps. There are thousands, if not tens of thousands, of steps within those basic steps. They all have to be done.

Q. The fifth step is FDA postmarket safety monitoring, right?

A. Yes.

Q. For that fifth step, would a company still be undertaking product development on the FDA cleared device?

A. I'm sorry? You'll have to ask me again.

Q. Sure. I'll scoot back over. I apologize. So talking about the fifth step in the FDA device development process, could a company still be undertaking product development on an FDA cleared device when it's in the fifth step of the FDA device development process?

A. I think you're asking could a company undertake product development while a product is cleared for marketing?

Q. Correct.

A. Yes, but it would be difficult to introduce a product with different configuration to the market without getting regulatory clearance, and the FDA provides guidance on how much a company can do without seeking regulatory clearance in advance, and how much has to be done. It's a judgment call.

(Tr. (Crosby) at 663:6-668:22.).

Respondents did not dispute ***any*** aspects of Mr. Crosby's testimony explaining this regulatory clearance process or raise ***any*** arguments about this general procedure. (*See, e.g.*, RPBr. at 16-18; RBRr. at 7-19.). On cross-examination, with respect to the specific issue of the regulatory clearance process, Respondents only asked Mr. Crosby the following questions, none of which were directed to specifically rebutting Mr. Crosby's direct testimony with respect to the same.

Q. . . . Earlier today you testified about the FDA process for approving medical devices, right?

A. Yes.

Q. And you talked about the five steps that are involved in that, correct?

A. This is the FDA's explanation of some of the -- of the five steps as they see it.

Q. Once a device receives a 510 clearance, it can be marketed consistent with that clearance, right?

A. The 510(k) clearance, yes.

Q. And the FDA clearance only regulates how a product can be marketed through its label, right? It doesn't preclude, for example, physicians using a device for off label purposes.

A. The FDA does not regulate the practice of medicine. It regulates the devices that medical practitioners use.

Q. Okay. And so once a product is cleared by FDA, you then move into step 5 on slide CDX 1C.110, right?

A. Yes.

Q. And do you understand that the party that was responsible for getting the domestic industry product, the Sylfirm X, cleared through steps 1 through 4, that was the Korean manufacturer, ER, are you aware of that?

A. I read the 510(k) application. I don't recall who was responsible for all the steps.

Q. You're not giving an opinion today that Benev was the party that was responsible for getting the Sylfirm X cleared in the United States, right?

A. That's not part of my assignment, no.

Q. And then you testified about a bunch of things that can happen after the product is cleared for additional indications under step 5.

Do you remember that?

A. Yes.

Q. You didn't testify today about any of the actual work that Benev has done to secure clearances for those additional indications, right?

[redacted]

MR. MCCRUM: Okay. That's actually all I wanted to confirm, Your Honor.

JUDGE MCNAMARA: Okay. Thank you.

MR. MCCRUM: I have no further questions, Mr. Crosby.

(Tr. (Crosby) at 656:23-658:24.).

**b)** [redacted]

Respondents unequivocally [redacted]. (Tr. (van der Weide) at 292:3-295:19; CDX-0004C.0056-67 (van der Weide demonstratives); CX-0166C.0017 (Potenza 510(k)) [redacted] (emphasis added), 0022 (Potenza 510(k)); CX-0339C.0013 (Intensif 510(k)) [redacted] (emphasis added), 0017 (same), 0023 (Intensif 510(k)).).

**Figure 9: Respondents' Representations to FDA in 510(k) Submissions with Respect to Intended Use**



(CDX-0004C.0057 (excerpting CX-0166C.0017 (Potenza 510(k)) (annotated); CX-0339C.0013 (Intensif 510(k)) (annotated)).).

In their . (Tr. (van der Weide) at 295:20-296:7; CX-0166C.0045 (Potenza 510(k)) (emphasis added); CX-0339C.0048 (Intensif 510(k)) (emphasis added).).

**Figure 10: Respondents' Representations to FDA in 510(k) Submissions**



(CDX-0004C.0064 (excerpting CX-0166C.0045 (Potenza 510(k)) (annotated); CX-0339C.0048 (Intensif 510(k)) (annotated)).).

Notably, each of the . As depicted

below, [redacted] (Tr. (van der Weide) at 292:3-295:19; CDX-0004C.0056-67; CX-0166C.0017, 0022 (Potenza 510(k)); CX-0339C.0013, 0023 (Intensif 510(k)).).

**Figure 11: Verifications of Respondents' 510(k) Submissions**

[redacted]

[redacted]

(*See* CDX-0004C.0061 (excerpting CX-0166C.0017, 0022 (Potenza 510(k)) (annotated)); CDX-0004C.0063 (excerpting CX-0339C.0013, 0023 (Intensif 510(k)) (annotated)); *see also* Tr. (van der Weide) at 293:4-294:2 (testifying that Respondents' arguments that their products do not cause coagulation is "at variance" with "sworn representation[s] before the FDA").).

As Staff pointed out, even Respondents' expert, Dr. Brennan, would not go so far as to say that Respondents' FDA submissions and product literature are not truthful or accurate, or that those documents falsely represented the products.

[redacted]

[redacted]

(Tr. (Brennan) at 1191:1-1192:1; *see also id.* at 1192:2-1198:11.).

Moreover, Respondents' expert, Dr. Bérubé, agreed that it is important to avoid misleading the audience (medical professionals and patients) in marketing FDA-approved devices, such as the Accused Products.

> Q. . . . Yes or no, Dr. Berube, you agree that it's important to avoid misleading people in marketing an FDA approved device to the public, right?
>
> A. Yes.
>
> Q. Okay. And you agree that the audience for marketing FDA approved RF microneedling devices includes medical professionals and potential patients, right?
>
> A. Right.

(Tr. (Bérubé) at 1270:1-9.).

Unable to completely dismiss these explicit admissions to the FDA, during the Hearing, Respondents ineffectively attempted to suggest that their sworn representations were potentially ***inaccurate***.

> MR. MCCRUM: I am suggesting, Your Honor, the Respondents submitted 510(k) statements based on a predicate product, and that it is not uncommon that, when you do that, that you are taking portions of that and cutting it into your own.
>
> JUDGE MCNAMARA: On this one, I suggest you move on. I will talk to you about this later. If you have an offer of proof that is somehow relevant and suggests

that the -- ***what I'm hearing you say is the 510(k) summaries, that the parties themselves submitted to the FDA, are not accurate***. Is that what you are saying?

MR. MCCRUM: ***I am saying there's evidence to suggest that***, Your Honor.

JUDGE MCNAMARA: Well, if that is the case, that's on Respondents, and I think you have to think about what it is they submitted to the FDA and what it is you're saying here.

MR. MCCRUM: Okay.

JUDGE MCNAMARA: I think you have to think through the implications of this.

MR. MCCRUM: Understood, Your Honor.

(Tr. at 438:3-23 (emphases added).).

In what appeared to be another attempt to further undermine their own sworn FDA filings, their expert, Dr. Woloszko (whose direct examination was presented, and thereby endorsed, by all Respondents), resisted answering whether a company would submit misleading information to the FDA.

Q. . . . You would not give the FDA misleading information, right?

A. You give FDA the information they require in the form that they require.

Q. And you would not give the FDA misleading information, correct?

A. Again, you give FDA the information they ask for. You answer the question.

Q. And when you answer the question, you don't give them misleading information, do you.

A. ***I'm not answering that question***.

(Tr. (Woloszko) at 1024:18-1026:3 (emphasis added).).

Following that response, Dr. Woloszko was impeached with his deposition testimony where he had expressly answered "***definitely not***" in response to the question, "[b]ut you wouldn't give the FDA misleading information, right?"

Q. Okay. Well, you did answer it at the deposition, so let's take a look at that.

Can we go to CX 3064 at 35. This is the September 14th deposition, page 264, lines 1 3.

But you wouldn't give the FDA misleading information, right? The answer, "***definitely not***."

A. Yes.

Q. Did I read that correctly?

A. You don't want to on purpose lead the FDA to believe something which would be wrong, yes, true. You would not volunteer information even if it may be in your favor if they don't ask it. That's -- they don't ask for it.

Q. But you understand that the FDA 510(k) submissions are certified to be truthful and accurate, right?

A. Absolutely.

Q. You would not expect that the Respondents would give the FDA misleading information, right?

A. ***You would not lie to FDA, definitely not***.

(Tr. (Woloszko) at 1026:4-23 (emphases added).).

As Staff noted, either Respondents were contending that their documents do ***not*** say what they plainly do, or Respondents were contending that their representations to the federal government and to the public contain ***false*** statements and information. (SBr. at 25.). Either way, Respondents' attempts to dismiss or walk away from how ***they have characterized the Accused Products to the FDA*** are not only unpersuasive, but also, run dangerously close to crossing ethical lines of transparency that were required when making representations to the FDA to obtain regulatory clearance of the Accused Products.

### 3. Infringement Overview

Serendia asserted that the Accused Products directly infringe claims 1, 9, and 22 of the '836 patent. (CBr. at 11.). For the reasons discussed below, Serendia has met its burden and

proven that the Accused Products directly infringe claims 1, 9, and 22.

#### 4. The Accused Products Practice Claim 1 of the '836 Patent

##### a) 1[pre]: "A skin treatment apparatus, comprising"

Each Accused Product is a "skin treatment apparatus," which Respondents admitted. (Tr. (van der Weide) at 280:15-25, 281:8-13; CDX-0004C.0024, 0026; CX-0876C.0002-3, 0011 (EndyMed RFA Resp.).).

Respondents did not contest that the Accused Products are skin treatment apparatuses in their Pre-Hearing Brief or Post-Hearing Reply Brief. (RPBr. at 12-19; RRBr. at 4-42.). Thus, any argument on this issue is deemed abandoned, withdrawn, and/or waived under Ground Rules 7.2 and 10.1.

For the foregoing reasons, Serendia has proven by a preponderance of evidence that the Accused Products meet the preamble of claim 1 of the '836 patent.

##### b) 1[a]: "a plurality of electrodes, the electrodes being bipolar and configured to be insertable into skin to be treated"

The claim term "a plurality of electrodes" was construed to have its plain and ordinary meaning: "two or more electrodes (which can be needles or pins)." (*Markman* Order at 45.). Respondents admitted, and inspections demonstrate, that the Accused Products include "two or more electrodes (which can be needles or pins)." (Tr. (van der Weide) at 281:14-282:11; CDX-0004C.0027-30; CX-0876C.0011-12 (EndyMed RFA Resp.); CX-2939C.0008, 0014-20, 0028-32 (Inspections).). Additionally, Respondents' marketing materials and corporate deposition testimony confirm that the Accused Products meet this limitation. (CPX-0071 (Potenza Video) at 0:08-0:10; CX-1050C (Kyoung Ho An Dep. Tr.)[29] at 45:14-19, 47:20-50:12, 52:1-11, 65:15-

[29] [redacted]

66:3; CPX-0067 (Intensif Video) at 0:17, 0:45; CX-1056C (Sima Witman Dep. Tr.)[30] at 113:11-114:8.).

In their Pre-Hearing Brief, Respondents only disputed that this aspect of limitation 1[a] was met under Respondents' proposed construction limiting the term to non-insulated electrodes, which was rejected. (RPBr. at 5-6; *Markman* Order at 45.). Thus, Respondents abandoned or withdrew any argument that this aspect of limitation 1[a] is not met under the adopted construction. (*See* G.R. 7.2.). Moreover, Respondents did not contest this aspect of limitation 1[a] in their Post-Hearing Reply Brief. (RRBr. at 4-42.). Accordingly, any argument on this issue is deemed waived under Ground Rule 10.1.

With respect to the claim term "electrodes being bipolar," the term was given its construed to have its plain and ordinary meaning: "electrodes change or alternate between being positive or negative as the current alternates between them (as opposed to a monopolar configuration where current flows from one or more electrodes that deliver current to one or more ground electrodes)." (*Markman* Order at 40.). Respondents represented that [redacted]. (RX-2015C (Potenza 510(k) Summary); CX-0339C (Intensif 510(k)).). As Serendia noted, the FDA defines "bipolar" as "[a]n electrosurgical device in which the current flows between two active electrodes placed in close proximity," consistent with the adopted construction. (CBr. at 12 (citing CX-1071 (FDA Premarket Notification 510(k) Guidance) at 26).).

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[redacted] (*See, e.g.*, CX-1050C (An Dep. Tr.) at 13:21-14:17.). [redacted] as a corporate representative. (*Id.* at 11:11-14.). [redacted] also testified in his personal capacity. (*Id.*).

30 [redacted] (CX-1056C (Witman Dep. Tr.) at 32:19-33:10.). EndyMed designated [redacted] to testify with respect to certain topics on behalf of EndyMed. (*Id.* at 22:9-12.).

Serendia's expert, Dr. van der Weide, testified that he reviewed Respondents' FDA filings, internal documents, and corporate representatives' testimony, and concluded that the Accused Products practice this limitation. (Tr. (van der Weide) at 282:12-285:2, 288:25-289:5; CDX-0004C.0032-34, 44-47; CX-2906C.0004, 0016 (Potenza Histology Presentation); CX-1052C (Lowinn Kibbey Dep. Tr.)[31] at 18:3-5; CX-1050C (An Dep. Tr.) at 97:1-5; CX-0233C.0049 (Potenza Slides); CX-0805.0009 (Potenza Physician Brochure); CX-1056C (Witman Dep. Tr.) at 168:7-170:2, 228:3-5.). He also measured the Accused Products' waveforms and confirmed that they practice this limitation. (Tr. (van der Weide) at 284:18-285:2; CDX-0004C.0034; CX-2939C.0017-20, 0030-32 (Inspections).).

The combined term "a plurality of electrodes, the electrodes being bipolar," was construed to exclude "the Intracel configuration (alternating rows of commonly-polarized electrodes)." (*Markman* Order at 53-54.). Dr. van der Weide testified that he inspected the electrode configurations for Accused Products and determined that they are not the Intracel configuration. (Tr. (van der Weide) at 287:20-289:5; CDX-0004C.0044-47; CX-0064C.0002-3 (EndyMed Rog. Resp.); CX-0233C.0049 (Potenza Slides).). In their Pre-Hearing Brief and Post-Hearing Reply Brief, Respondents did not dispute that the Accused Products practice the "electrodes being bipolar" part of limitation 1[a] and did not contend that any of them have the Intracel configuration. (RPBr. at 6-10; RRBr. at 4-42.). Thus, any argument on this issue is deemed abandoned, withdrawn, and/or waived under Ground Rules 7.2 and 10.1.

Lastly, Serendia demonstrated, and Respondents did not dispute, that the plurality of

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31 [redacted] (CX-1052C (Kibbey Dep. Tr.) at 16:6-9.).

electrodes are "configured to be insertable into skin to be treated."[32] (Tr. (van der Weide) at 289:14-20; CDX-0004C.0048-49; CX-2939C (Inspections).). Accordingly, any argument on this issue is deemed abandoned, withdrawn, and/or waived under Ground Rules 7.2 and 10.1.

For these reasons, Serendia has proven by a preponderance of evidence that the Accused Products meet this limitation of claim 1 of the '836 patent.

**c) 1[b]: "a radio frequency (RF) generation module, the RF generation module electrically coupled to the plurality of electrodes and configured to provide an Alternating Current (AC) RF signal to the plurality of electrodes configured to cause coagulation around each electrode rather than coagulating between the electrodes"**

The Accused Products have a "radio frequency (RF) generation module, the RF generation module electrically coupled to the plurality of electrodes," which Respondents admitted. (CX-0925C.0012 (Potenza RFA Resp.); CX-0876C.0009 (EndyMed RFA Resp.); Tr. (van der Weide) at 289:21-290:19; CDX-0004C.0050-52.). Respondents did not dispute that the Accused Products meet this aspect of limitation 1[b]. (RPBr. at 6-19; RRBr. at 4-42.). Accordingly, any argument on this issue is deemed abandoned, withdrawn, and/or waived under Ground Rules 7.2 and 10.1.

The term "an Alternating Current (AC) RF signal" was given its plain and ordinary meaning: "an electrical signal with oscillating current (current alternating polarities), and having a radio frequency (measured in MHz)." (*Markman* Order at 62.). As Dr. van der Weide testified, Respondents' admissions, documents, FDA submissions, and corporate testimony demonstrate that the Accused Products practice this aspect of limitation 1[b]. (Tr. (van der

[32] The term "configured to" was construed to have its "[p]lain and ordinary meaning: adapted to." (*Markman* Order at 39.).

Weide) at 290:20-292:2; CDX-0004C.0053-55; CX-0925C.0012 (Potenza RFA Resp.); CX-0233C.0047 (Potenza Slides); CX-0166C.0032-33 (Potenza 510(k)); CX-1050C (An Dep. Tr.) at 56:4-57:18, 58:19-60:1; CX-0876C.0009-10 (EndyMed RFA Resp.); CX-0703C.0034 (EndyMed Rpt.); CX-1056C (Witman Dep. Tr.) at 77:16-19, 81:13-16, 170:4-21; CX-0696.0012, 0058-59 (EndyMed Manual).). Dr. van der Weide also measured the Accused Products' waveforms, confirming that they provide AC RF signals. (Tr. (van der Weide) at 290:20-292:2; CDX-0004C.0053-54; CX-2939C.0010-13, 17-20, 30-32 (Inspections).). Respondents only disputed that the Accused Products practice this limitation under their proposed construction, which was rejected. (RPBr. at 10-12; *Markman* Order at 56-62.). Accordingly, Respondents abandoned or withdrew any argument on this issue under Ground Rule 7.2.

The term "electrodes configured to cause coagulation around each electrode rather than coagulating between the electrodes" (the "coagulation term") was construed to have its plain and ordinary meaning: "two or more electrodes adapted to cause coagulation around each electrode without such coagulation fully extending from one electrode to another electrode." (*Markman* Order at 40.). As discussed below, the evidence, including Respondents' own, verified representations to the FDA in seeking regulatory approval for the Accused Products, Respondents' internal and external product literature, and expert testimony from Dr. Goldberg and Dr. van der Weide, demonstrate that the Accused Products satisfy the coagulation limitation.

As addressed above in Section VII.A.2, Respondents [redacted] (Tr. (van der Weide) at 292:3-295:19; CDX-0004C.0056-67; CX-0166C.0017 [redacted]

(emphasis added), 0022 (Potenza 510(k)); CX-0339C.0013 (emphasis added), 0017 (same), 0023 (Intensif 510(k)).). Respondents also . (Tr. (van der Weide) at 295:20-296:7; CDX-0004C.0064; CX-0166C.0045 (Potenza 510(k)) (emphasis added); CX-0339C.0048 (Intensif 510(k)) (emphasis added).). Each of the (Tr. (van der Weide) at 292:3-295:19; CDX-0004C.0056-67; CX-0166C.0017, 0022 (Potenza 510(k)); CX-0339C.0013, 0023 (Intensif 510(k)).).

Serendia's expert, Dr. Goldberg, reviewed the evidence and concluded that the Accused Products are configured to cause coagulation around each electrode without such coagulation fully extending between the electrodes.[33] (Tr. (Goldberg) at 173:3-175:25 (Potenza), 179:14-24 (EndyMed); CDX-0002C.0024-30, 0038-40.). For each Accused Product, Dr. Goldberg compared the maximum width of electrocoagulation zones measured during preclinical tests with the minimum distance between needles, which demonstrated that in ***every*** instance the coagulation zones did ***not*** fully extend between neighboring electrodes. (Tr. (Goldberg) at 173:3-175:8, 179:17-20; CDX-0002C.0025-29, 38-40; CX-0172C.0004 (Potenza Performance Rpt.); CX-2907C.0019-20, 0023 (Potenza Eval.); CX-0690C.0007-8 (EndyMed Description).).

[33] Serendia claimed accurately that Dr. Goldberg was the only dermatologist who testified, and the only expert who used the Accused Products in a clinical setting. (CBr. at 16; *see also* SBr. at 36.).

As Dr. Goldberg testified, internal documents and deposition testimony from Respondents' corporate representatives confirm that the Accused Products are configured to cause coagulation around each electrode without such coagulation fully extending between electrodes. (Tr. (Goldberg) at 173:12-22, 179:25-180-13; CDX-0002C.0025, 0039.).

For example, with respect to the [redacted] (CX-0690C.0008) [redacted]. (CX-1056 (Witman Dep. Tr.) at 178:19-179:7.).

Similarly, for the Potenza Products, an internal evaluation concluded that [redacted] (CX-2907C.0023 (Potenza Eval.); *see also id.* at 18 [redacted], 19 (pictures of same).). EndyMed's internal evaluation explained that [redacted] (*Id.* at 18.).

After the Hearing, Jeisys/Cynosure specifically argued that the Potenza "S-49 tip does not produce the claimed coagulation."[34] However, this is directly contrary to: (i) their own test results which reflect and support the opposite conclusion, i.e., that it does (CX.2907.0019); and (ii) how they tell clinicians their "S tips" function (CX-0962.0018 (Potenza Clinical Ref. Guide) (depicting "horizontal areas" of "coagulation" for "S-Tips" around each needle and not between needles)).).

[34] Respondents Jeisys Medical, Inc.'s and Cynosure, LLC's Reply to Staff's Post-Hearing Notice, Doc. ID No. 810861 at 3 (Dec. 21, 2023).

As Dr. Goldberg testified credibly, Jeisys/Cynosure market their products as concentrating energy and/or causing coagulation around needle electrodes, rather than between them, which matches how he understands these products work. (Tr. (Goldberg) at 175:9-25; CDX-0002C.0030 (Goldberg); CPX-0060 (Potenza YouTube) at 1:41.). Dr. Goldberg also credibly testified that the evidence he reviewed (discussed above), aligns with his personal experience with the EndyMed Products in his practice. (Tr. (Goldberg) at 180:21-24.).

Dr. van der Weide similarly reviewed the evidence that Dr. Goldberg reviewed and described and considered the testimony of Drs. Goldberg and Na. Dr. van der Weide concluded that the Accused Products practice this limitation. (Tr. (van der Weide) at 296:10-297:25; CDX-0004C.0066-67, 0083.).

Specifically, EndyMed [redacted] EndyMed's responses to Serendia's Request for Admission ("RFA") No. 25 is reproduced below.

**Figure 12: EndyMed Response to RFA**

[redacted]

(CDX-0004C.0066 (citing CX-0876C.0017-18 (EndyMed RFA Resp.)).).

EndyMed's admission is consistent with the weight of other evidence that conclusively reflect how EndyMed's Accused Products operate. (*See, e.g.*, Tr. (Goldberg) at 179:18-180:24,

183:1-9 (EndyMed Accused Devices are configured to cause coagulation around each electrode rather than between electrodes); Tr. (van der Weide) at 295:14- 297:11 (similar).). For example, in Order No. 49, which denied EndyMed's motion to withdraw its response to RFA No. 25, EndyMed's corporate testimony was found to "align[] with EndyMed's admission in its RFA No. 25 Response that the Accused Products have been used to apply energy to cause coagulation around each electrode." (Order No. 49 at 6-7 (Nov. 30, 2023) (citing CX-1056 (Witman Tr.) at 181:8-182:1, 185:8-19).). The admission also

. (CX-3411.0001, 0003 (EndyMed article); Tr. (Woloszko) at 1028:22-1029:5, 10:29:22-1030:4, 1031:17-22.).

In addition, Dr. van der Weide

. (Tr. (van der Weide) at 298:1-302:19; CDX-0004C.0069-73; CX-2936C (Heatmapping Tests).). Those

(Tr. (van der Weide) at 302:6-9; CDX-0004C.0072.). Dr. van der Weide's testing was published as part of a peer-reviewed study and was presented at an IEEE conference in Belgium. (Tr. (van der Weide) at 321:6-24; CX-3055 (IEEE Article).). Moreover, as Dr. van der Weide testified, the

[35] (Tr. (van der Weide) at 302:10-19.).

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[35] Serendia represented accurately that its expert, Dr. van der Weide, was the only expert who tested the Accused Products. (CBr. at 19 (citing Tr. (van der Weide) at 299:10-13).).

Respondents contended that none of their Accused Products infringe the coagulation limitation for three (3) reasons: (1) Serendia improperly relied on Respondents' submissions to the FDA and Respondents' product literature to prove infringement, and/or that those documents do not demonstrate the claimed coagulation around (but not between) electrodes; (2) Dr. van der Weide's testing evidence is unreliable and not probative of infringement; and (3) all of their products cause skin temperature to increase between electrodes as the current moves between electrodes such that the recited coagulation necessarily occurs between electrodes. (*See* RPBr. at 12-19.). These arguments are meritless for the following reasons.

First, as discussed above in Section VII.A.2, Respondents' arguments with respect to their own documents are premised on dismissing or walking away from (i.e., ***contradicting***) how ***they have characterized the Accused Products to the FDA***, in their internal documentation, and to the public. As Staff noted, either Respondents are contending that their documents do not say what they plainly do, or Respondents are contending that their representations to the federal government and to the public contain false statements and information. (SBr. at 25.). As noted above in Section VII.A.2, [redacted]. (*See* Fig. 11, *infra*.).

Respondents asserted that "the pre-clinical testing Respondents submitted to the FDA, while consistent with the FDA's guidelines, is not evidence of 'coagulation around each electrode without such coagulation fully extending from one electrode to another electrode' in the skin." (RRBr. at 15.). Dr. Brennan testified that "kidney, liver, and [the] muscle of a cow" used for preclinical testing of the Potenza does not support infringement because it is not "human skin." (Tr. (Brennan) at 1157:9-24.).

The record evidence does not support Respondents' position. Indeed, is directly contrary to Dr. Brennan's testimony. Notably, the FDA accepts testing "performed on ***ex vivo animal tissue***" to clear RF microneedling devices for use on human skin and in fact recommends using "liver, kidney, and muscle tissue," with which Respondents' expert agreed.[36] (CX-1071.0017 (FDA Premarket Notification 510(k) Guidance) ("during testing in *ex vivo* tissue . . ."); *id.* ("during *ex vivo* tissue testing . . ."); Tr. (Woloszko) at 1023:11-14 ("Q. You understand that the FDA accepts histology on animal tissue as part of the information for clearing RF microneedling devices, right? A. Correct."), 1024:9-15; *see also* Tr. (van der Weide) at 330:16-331:2; CDX-0004C.0080.). Dr. Goldberg, Serendia's expert, also confirmed both he and the FDA rely on animal testing as indicative of how a product will function on humans. (Tr. (Goldberg) at 168:6-9.).

[redacted]. (CX-0174C.0005 [redacted]; CX-2907.0020 (Potenza Eval.) (depicting

[36] Respondents argued that the FDA "*ex vivo* animal tissue is ***not*** the same as skin" because in 2020, the FDA "amended its guidance documents to require, for 'specific soft tissue indications,' that 'testing should be performed in tissues relevant to the specific indications for use.'" (RRBr. at 15-16 (citing RX-0512.0016 (FDA Premarket Notification 510(k) Guidance); CX-1071.0016 (FDA Premarket Notification 510(k) Guidance).). Respondents' reading of the quoted language from the FDA Guidelines is not consistent with language on the next page the FDA Guidelines specifically referencing "testing on *ex vivo* tissue" and "*ex vivo* tissue testing," which strongly suggests the contrary. (CX-1071.0017 (FDA Premarket Notification 510(k) Guidance).).

[redacted].).[37]

Serendia also noted that during the Hearing, Dr. Woloszko testified that: (i) the FDA Premarket Notification Guidance distinguishes "coagulation" from "coagulation necrosis"; (ii) the '836 patent is directed to "coagulation necrosis"; and (iii) Respondents' FDA filings do not use that term. (CRBr. at 24.). Dr. Woloszko's testimony to which Serendia cited is reproduced below.

> Q. Does the FDA provide a definition for coagulation?
>
> A. Yes, they do. For FDA coagulation is used for liquid, especially blood, and basically this is very – this is very similar to hemostasis, although it's a different process.
>
> And they say this is considered separate from coagulation necrosis. Coagulation necrosis, as explained on the line below, is when necrosis will affect cells or tissue and convert them into a dry, opaque mass, which is basically what we have discussed over the past several days, as tissue coagulation.
>
> So tissue coagulation, as it says, is a result of protein coagulation. That is what we have discussed all along. We have not discussed so far liquid or blood coagulation.
>
> Q. So there's a difference between coagulation on the one hand and coagulative necrosis on the other?
>
> A. Yes.
>
> Q. And, generally speaking, are the '836 patent family directed to coagulation necrosis as opposed to coagulation?
>
> A. That's what FDA considers as coagulation necrosis.
>
> Q. And are Respondents' products cleared for use as coagulation devices?
>
> A. Yes.
>
> Q. Did the FDA clear the Respondents' products for coagulation necrosis?

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[37] Serendia noted that "[i]t is unclear where the study involving human skin was conducted." (CBr. at 31 n.22.). Dr Na testified that he tested animal tissue to develop the invention because testing human tissue is "not ethical." (Tr. (Na) at 82:16-83:3; *see also* Tr. (Goldberg) at 167:20-168:5 (studies are "invariably . . . done on animals" since "FDA would never allow a study to be done on a human").).

A. I have not seen any of these reference in any of the 510(k) I've reviewed.

(Tr. (Woloszko) at 997:2-998:7.).

Serendia contended that because Respondents were "[u]nable to dodge their own sworn FDA filings," Respondents "engage[d] in semantics, seeking to differentiate references to 'coagulation' in their FDA filings from the 'coagulation' claimed in the '836 Patent." (CRBr. at 24.). In their own Post-Hearing Reply Brief, Respondents criticized Serendia's contention that Respondents were arguing for a special meaning of coagulation in the context of their FDA submissions, an argument that Serendia alleged was not included in Respondents' Pre-Hearing Brief. (RRBr. at 9 (citing CBr. at 24-26).). Respondents stated that "Dr. Woloszko's testimony that the FDA guidance (RX-0512) defines 'coagulation' and 'coagulation necrosis' in different and particular ways (Tr (Woloszko) 997:2-20; RX-0512.0027) merely emphasizes that the general indication for 'electrocoagulation' provided by the FDA for the Accused Products is broader than just 'coagulation necrosis,' which in turn is broader than the specific result that is claimed by the '836 patent: coagulation necrosis around each electrode, but not between electrodes." (RRBr. at 9-10.).

Dr. Woloszko's supposed clarification of "coagulation" and "coagulation necrosis" does not meaningfully bolster Respondents' non-infringement argument. As Serendia noted, Dr. Woloszko and Respondents attempted to make a false distinction. (CRBr. at 24.). Both Respondents' FDA filings and the '836 patent are about coagulation of tissue, not coagulation of blood. (Tr. (Goldberg) at 1305:14-24.). Serendia pointed out the FDA definition on which Respondents relied explains that the thermal damage zones depicted in Respondents' preclinical tests ***is coagulation necrosis***. (CX-1071.0016 (FDA Premarket Notification 510(k) Guidance) Guidance) ("you should provide a measurement (under magnification) of the size (length, width,

and depth) of the ***thermal damage zone***, i.e***., coagulation necrosis***.").). Dr. Woloszko conceded as much on cross examination. (Tr. (Woloszko) at 1070:11-14 ("Q. Again, in this section, the FDA 510(k) guidance document [CX-1071.0016] refers to thermal damage zone as coagulation necrosis, right? A. Correct.").).

Second, Respondents asserted that Dr. van der Weide's heatmapping tests are "unreliable and not probative of infringement." (RPBr. at 13-16, RRBr. at 7-8, 36-39.). However, as Serendia pointed out, the heatmapping tests, which are just one piece of evidence supporting an infringement finding, are reliable because: (1) they resulted from actual experimentation, not mere theory or simulation; (2) they used the protocol for a peer-reviewed study and were presented at a respected academic conference; (3) the results align with Respondents' own marketing; and (4) the results match the preclinical tests for each Accused Product. (Tr. (van der Weide) at 433:22-25; 421:3-20; CX-3055 (IEEE Article).). *See also Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 580 (1993), which while it does not apply in administrative proceedings, nonetheless provides guidance here (indicators of reliability include: (i) whether the theory has been tested; (ii) whether the theory has been subjected to peer review and publication; (iii) the known or potential error rate, and standards controlling its operation; and (iv) whether the theory has been accepted in the scientific community). As discussed above, the heatmapping tests that Dr. van der Weide performed reflect where the RF energy is applied, that is, it is concentrated around the needle electrodes rather than between them.

Respondents' expert, Dr. Woloszko, testified that the heatmapping tests are unreliable because live human tissue differs from the test specimen. (Tr. (Woloszko) at 994:13-996:5.). On cross-examination, Dr. van der Weide agreed that there are always variations between different samples, even between humans. (Tr. (van der Weide) at 357:25-358:5.). However,

Respondents did not address why testing human tissue would have yielded different results or what material impact, if any, this would make. As noted above, the FDA does ***not*** require human testing to clear RF microneedling devices for electrocoagulation. (CX-1071.0015-17 (FDA Premarket Notification 510(k) Guidance) (requiring testing in animal tissue as part of 510(k) clearance process); *see also* Tr. (Woloszko) at 1024:9-15 ("Q. Just to make sure the record is clear. The FDA accepts testing on liver, kidney, and muscle tissue for a microneedling system for a general indication under its 2020 guidelines, right? A. General indication -- ***general without specific tissue***. So without mentioning skin, that's what general indication is for FDA, yes.") (emphasis added).).[38]

Respondents also contended that operating parameters used in the heatmapping testing can differ from those used in a clinical setting. For example, EndyMed argued that Dr. van der Weide [redacted].[39] (RPBr. at 15; RRBr. at 40-42.). However, as the [redacted]. (CX-2936C.0005, 0008 (Heatmapping Tests).). EndyMed did not explain why using [redacted] would make any difference.

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[38] Additionally, Respondents pointed out that Dr. van der Weide used a processed Oscar Mayer turkey lunch meat instead of mammalian tissue. (RPBr. at 13; RRBr. at 37.). Respondents asserted that "lunchmeat is neither 'skin' . . . nor a suitable substitute." (RPBr. at 13; *see also* RRBr. at 37 ("lunch meat is not 'skin'").). That the lunch meat Dr. van der Weide was not "skin" or an appropriate substitute, as Respondents contended, does not materially undermine the validity of his test results. As mentioned above, the results were published as part of a peer-reviewed study and presented at an IEEE conference. (Tr. (van der Weide) at 321:6-24; CX-3055 (IEEE Article).). Dr. van der Weide also confirmed that he did not need to perform the heatmapping tests to reach his conclusions with respect to coagulation and infringement of claim 1 of the '836 patent. (Tr. (van der Weide) at 298:20-8.).

[39] EndyMed did not provide an expert to opine that its Accused Products do not infringe the Asserted Patents. Therefore, Serendia's experts' opinions are unrebutted. EndyMed's arguments amount to little more than attorney argument and are contrary to statements and submissions EndyMed made to the FDA.

Furthermore, during the Hearing, EndyMed [redacted]. (Tr. (Yonay) at 406:19-408:7.). This is yet another example of Respondents contradicting their own documents. As Dr. van der Weide testified, [redacted]. (Tr. (van der Weide) at 431:8-432:2 (discussing CX-0339C (Intensif 510(k))).).

As Dr. van der Weide testified, Respondents failed to produce a single piece of evidence demonstrating that coagulation extends fully between electrodes. (Tr. (van der Weide) at 428:6-10.). Despite having unfettered access to the Accused Products, Respondents' experts did not perform testing to try to support non-infringement arguments. (Tr. (van der Weide) at 299:9-15; Tr. (Woloszko) at 1022:14-21; Tr. (Brennan) at 1174:5-7.).

Third, Respondents argued that their marketing materials do not support a finding of infringement. For example, they contended that their marketing materials are not probative because they are artistic renderings. (Tr. (Brennan) at 1157:25-1158:13.). However, Respondents' corporate representatives testified that they strive to accurately represent the Accused Products' functionality in marketing materials. (*See, e.g.*, CX-1052C (Kibbey Dep. Tr.) at 124:3-125:9.). Even if their marketing materials do not consistently reflect how their products operate, their own preclinical testing, representations to the FDA, and admissions in this Investigation confirm that Respondents' Accused Products infringe. (CX-0172C.0004 [redacted]; CX-2907C.0018-20, 23 [redacted]; CX-0690C.0007-8 (Intensif 510(k) Description); CX-0876C.0017-18 (EndyMed RFA Resp.).).

Respondents' expert, Dr. Brennan, also testified that some marketing materials demonstrate that when needles are applied to skin, there is energy between electrodes. (Tr.

(Brennan) at 1158:1-13.). As Serendia pointed out, Respondents did not identify any ***evidence*** of coagulation between needles. (CBr. at 28.). A device still infringes even if it is sometimes capable of achieving other results. *Broadcom*, 732 F.3d at 1333; *Bell Commc'ns Research*, 55 F.3d at 622-23.

For the foregoing reasons, Serendia has proven by a preponderance of evidence that the Accused Products meet this limitation of claim 1 of the '836 patent.

**5. The Accused Products Practice Claim 9 of the '836 Patent**

**a) "The skin treatment apparatus of claim 1, wherein the electrodes are needles and have a diameter from 0.25 mm to 0.30 mm."**

It is uncontested that the Accused Products practice claim 9, which additionally requires that "the electrodes are needles and have a diameter from 0.25 mm to 0.30 mm." (Tr. (van der Weide) at 332:10-333:9; CDX-0004C.0084-85, 88; *see also* CX-0805.0009 (Potenza Physician Brochure); CX-1050C (An Dep. Tr.) at 101:5-15; CX-0690C.0006 (Intensif 510(k) Description); CX-0697C.0022 (EndyMed Technical Details); CX-0700C (EndyMed Needle Drawing).).

In their Pre-Hearing Brief and Post-Hearing Reply Brief, Respondents did not dispute that the additional requirement of this claim is practiced. (RPBr. at 20-21; RRBr. at 4-42.). Thus, any argument on this issue is deemed abandoned, withdrawn, and/or waived under Ground Rules 7.2 and 10.1.

Accordingly, Serendia has proven by a preponderance of evidence that the Accused Products meet the additional limitation recited in claim 9 of the '836 patent.

**6. The Accused Products Practice Claim 14 of the '836 Patent**

**a) 14[pre]: "A method of treating skin, comprising"**

**14[a]: "inserting a plurality of electrodes, the electrodes being bipolar into a section of skin to be treated"**

**14[b]: "applying a Alternating Current (AC) Radio Frequency (RF) signal to the plurality of electrodes configured to cause coagulation around each electrode rather than coagulating between the electrodes"**

Asserted claim 22 depends from independent claim 14, which is no longer at issued in this Investigation. Claim 14 is a method claim of apparatus claim 1. Because there are no material differences for purposes of this analysis, the Accused Products satisfy claim 14 for the same reasons discussed above for claim 1. (Tr. (van der Weide) at 334:1-5; *see* Section VII.A.4, *supra*.).

Respondents did not make any specific arguments with respect to the limitations recited in claim 14 in either their Pre-Hearing Brief or Post-Hearing Reply Brief nor did they provide rebuttal evidence. (RPBr. at 21; RRBr. at 4-42.). Thus, any argument on this issue is deemed abandoned, withdrawn, and/or waived under Ground Rules 7.2 and 10.1.

Accordingly, Serendia has proven by a preponderance of evidence that the Accused Products meet the preamble and practice the limitations of claim 14 of the '836 patent.

**7. The Accused Products Practice Claim 22 of the '836 Patent**

**a) "The method of treating skin of claim 14, wherein the RF is from 0.5 to 10 Mhz and the predetermined time interval is from 0.05 to 0.8 seconds."**

It is undisputed that, in the Accused Products, "the RF is from 0.5 to 10 MHz and the predetermined time interval is from 0.05 to 0.8 seconds." (Tr. (van der Weide) at 333:10-334:10; CDX-0004C.0088-90; *see also* CX-0720C.0022 (Potenza 510(k)); CX-0233C.0051, 0054, 0057 (Potenza Clinal Training Slides); CX-0805.0009 (Potenza Physician Brochure); CX-1050C (An Dep. Tr.) at 19:13-15, 61:9-63:20; CX-0339C.0057 (EndyMed 510(k)); CX-1056C (Witman Dep. Tr.) at 228:19-22.).

Other than the disputes they raised with respect to claim 1, Respondents did not dispute that this claim is practiced. (RPBr. at 21; RRBr. at 4-42.). Thus, any argument on this issue is deemed abandoned, withdrawn, and/or waived under Ground Rules 7.2 and 10.1.

For the reasons discussed above, Serendia has proven by a preponderance of evidence that the Accused Products meet the additional limitation recited in claim 22 of the '836 patent.

## B. Indirect Infringement

### 1. Legal Standard

#### a) Induced Infringement

"Whoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. § 271(b). A patentee who asserts a claim of inducement must prove (i) that there has been direct infringement and (ii) that the alleged infringer "knowingly induced infringement and possessed specific intent to encourage another's infringement." *Minnesota Mining & Mfg. Co. v. Chemque, Inc.*, 303 F.3d 1294, 1304-05 (Fed. Cir. 2002). With respect to the direct infringement requirement, the patentee "must either point to specific instances of direct infringement or show that the accused device necessarily infringes the patent in suit." *ACCO Brands, Inc. v. ABA Locks Mfrs. Co., Ltd.*, 501 F.3d 1307, 1313 (Fed. Cir. 2007) (citation omitted). This requirement may be satisfied by circumstantial evidence. *Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1326 (Fed. Cir. 2009). "[A] finding of infringement can rest on as little as one instance of the claimed method being performed during the pertinent time period." *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1317 (Fed. Cir. 2009); *Toshiba Corp. v. Imation Corp.*, 681 F.3d 1358, 1364 (Fed. Cir. 2012) (citing *Lucent Techs.*, 580 F.3d at 1317).).

The specific intent requirement for inducement necessitates proving that the alleged infringer was aware of the patent, induced direct infringement, and that he knew that his actions

would induce actual direct infringement. *Commil USA, LLC v. Cisco Sys., Inc.*, 720 F.3d 1361, 1367 (Fed. Cir. 2013), *aff'd and vacated in-part on other grounds*, 135 S. Ct. 1920, 1926-28 (2015); *Global-Tech Appliances, Inc. v. SEB S.A.*, 131 S. Ct. 2060, 2068-70 (2011). Specific intent can be proven by, for example: (1) changes in importation practices effectuated to shift infringement liability; (2) the infringer's copying of patented technology; and (3) the infringer's willful blindness of the underlying direct infringement. *Certain Network Devices, Related Software and Components Thereof (I)*, Inv. No. 337-TA-944, Initial Determination at 82; *see also Commil USA, LLC v. Cisco Sys., Inc.*, 135 S. Ct. 1920, 1924-25 (2015) ("It was not only knowledge of the existence of [the asserted] patent that led the Court to affirm the liability finding but also it was the fact that [the accused infringer] copied 'all but the cosmetic features of the [patented product],' demonstrating [the accused infringer] kn[ew] it would be causing customers to infringe [the asserted] patent.") (quoting *Global-Tech*, 131 S. Ct. at 2071).

Willful blindness, which also constitutes "knowledge," has two basic requirements: "(1) the defendant must subjectively believe that there is a high probability that a fact exists"; and "(2) the defendant must take deliberate actions to avoid learning of that fact." *Global-Tech*, 131 S. Ct. at 2070.

The intent to induce infringement may be proven with circumstantial or direct evidence and may be inferred from all the circumstances. *Commil*, 720 F.3d at 1366; *Global-Tech*, 131 S. Ct. 2071-72.ALH

**b) Contributory Infringement**

35 U.S.C. § 271(c) sets forth the rules for contributory infringement:

> Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination, or composition, or a material or apparatus for use in practicing a patented process,

> constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

35 U.S.C. § 271(c).

Specifically with respect to Section 337 investigations, the Federal Circuit has held that "to prevail on contributory infringement in a Section 337 case, the complainant must show inter alia: (1) there is an act of direct infringement in violation of Section 337; (2) the accused device has no substantial non-infringing uses; and (3) the accused infringer imported, sold for importation, or sold after importation within the United States, the accused components that contributed to another's direct infringement." *Spansion, Inc. v. Int'l Trade Comm'n*, 629 F.3d 1331, 1353 (Fed. Cir. 2010).

"[N]on-infringing uses are substantial when they are not unusual, far-fetched, illusory, impractical, occasional, aberrant, or experimental." *Vita-Mix*, 581 F.3d at 1327. To determine whether a use is substantial, an Administrative Law Judge may evaluate "the use's frequency, . . . the use's practicality, the invention's intended purpose, and the intended market." *i4i Ltd. Partnership v. Microsoft Corp.*, 598 F.3d 831, 851 (Fed. Cir. 2010). Section 271(c) also requires knowledge of the existence of the patent that is infringed. *Global-Tech*, 131 S. Ct. at 2068.

To satisfy the accused's contributory infringement's knowledge requirement, it is necessary to establish that "the accused contributory infringer knows that its component is included in a combination that is patented and infringing." This requires knowledge of the patent. *Id.* In addition, the Federal Circuit has held that it is not sufficient to know of the patent and the relevant acts, but must also know that "these acts constituted infringement." *Fujitsu Ltd. v. LG Elecs.*, 620 F.3d 1321, 1320 (Fed. Cir. 2010). For purposes of contributory infringement,

such knowledge is inferred where the article at issue has no substantial non-infringing uses. *See Certain Semiconductor Chips with Minimized Chip Package Size and Prods. Containing Same*, Inv. No. 337-TA-605, 2009 WL 8144934, at *28, Comm'n Determination (June 3, 2009).

Where infringement allegations address a "separate and distinct" feature of a product, the contributory infringement analysis (for example, with respect to the existence of non-infringing uses) may address the particular feature in question rather than the product as a whole. *See i4i Partnership v. Microsoft Corp.*, 598 F.3d 831, 849 (Fed. Cir. 2010); *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1320-21 (Fed. Cir. 2009); *Ricoh Co. Ltd. v. Quanta Comput. Inc.*, 550 F.3d 1325, 1338 (Fed. Cir. 2008).

**2. Indirect Infringement Overview**

Serendia alleged that Respondents indirectly infringe by inducing infringement and contributing to the infringement of the asserted claims of the '836 patent. (CBr. at 37-51.). For the reasons discussed below, Serendia has proven that Respondents indirectly infringe the asserted claims of the '836 patent.

**3. Acts of Direct Infringement**

**a) Jeisys and Cynosure**

Jeisys/Cynosure, and their customers have directly infringed the apparatus and method claims of the '836 patent by using the Potenza in the United States. For example, Cynosure [redacted]. (CX-0093C.0024 (Cynosure Rog Resp.) [redacted]. Similarly, Jeisys [redacted]. (CX-0722C (GLP Rpt.).). *Centillion Data Sys., LLC*

*v. Qwest Comm'ns Int'l, Inc.*, 631 F.3d 1279, 1284 (Fed. Cir. 2011). CX-0686C and CX-0174C

. (CX-0686C.0001, 0004, 0021 ; CX-0174C.0014 .). In the

. Likewise, CX-0174C

. (CX-0174C.0014 .).

. (CX-1052C (Kibbey Dep. Tr.) at 88:8-11.).

Additionally, Jeisys' and Cynosure's customers directly infringe by using the Potenza in the United States. (CX-0925C.0004 (Jeisys, Cynosure RFA Resp.)

(emphasis added).). For example, CX-0750C

. (CX-0750C ;

CX-1060C ( Dep. Tr.)[41] at 24:7-10.).

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[40] *See, e.g.*, Tr. (Dan Park) at 448:5-8 ("Q. What are KOLs? A. They are key opinion leaders . . . they are the doctors who actually use Sylfirm X and give us feedback and suggestions.").).

When he testified during the Hearing on November 2, 2023, Mr. Dan Park was the Chief Financial Officer of Benev. (CPSt. at 2-3.). Serendia identified Mr. Park as a fact witness to testify about "Benev's business operations in the United States, including business operations relating to the Domestic Industry Product, investments pertaining to its domestic industry, including its facilities and domestic operations in the United States." (*Id.* at 3.).

[41]

Respondents argued that "Cynosure does not perform any acts of direct infringement at the time of importation or at the time of sale to its customers in the U.S. because the accused Potenza products are imported and sold in an unassembled form where the tips are not attached to the handpiece." (RPBr. at 59.). Respondents' argument is "legally meritless" because there is no "at time of importation" requirement. *Certain Audio Players and Controllers, Components Thereof, and Prods. Containing the Same*, Inv. No. 337-TA-1191, Comm'n Op. at 18-22 (Feb. 1, 2022); *Certain Blood Cholesterol Testing Strips*, Inv. No. 337-TA-1116, Comm'n Op. at 25-26 (May 1, 2020) ("[Respondent's] argument that no violation exists because its products are not 'articles that infringe' at the time of importation has twice been rejected by the United States Court of Appeals for the Federal Circuit.").

Jeisys and Cynosure "cannot avoid liability" because the Potenza tips are imported unattached to the handpiece. *Certain Blood Cholesterol Testing Strips*, Comm'n Op. at 31 ("[respondent] cannot avoid liability based on the application of fluid to the test strips [after importation] in the United States"). Cynosure simply attaches the needle tips after importation and uses the assembled Potenza devices, which is sufficient to directly infringe both the asserted apparatus (claims 1 and 9 of the '836 patent) and method claim (claim 22 of the '836 patent). *See id.* at 29-31. As part of its [redacted] (CX-0686C.0005, 0008, 0009-10 (Clinical Report) [redacted]; *see also* CX-

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[redacted]. (CPSt. at 4.). Serendia identified [redacted] as a fact witness to testify generally about the "usage of certain Accused Products, including the . . . Potenza devices, and infringing acts of certain Respondents." (*Id.*).