February 7, 2020

Biomerics
Jake Wakley
Vice President of Quality and Regulatory
6030 West Harold Gatty Drive
Salt Lake City, Utah 84116

Re: K190259
Trade/Device Name: Vesta RF Cannula
Regulation Number: 21 CFR 882.4725
Regulation Name: Radiofrequency Lesion Probe
Regulatory Class: Class II
Product Code: GXI
Dated: January 3, 2020
Received: January 8, 2020

Dear Jake Wakley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Matthew C. Krueger -S

Matthew Krueger, M.S.E.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190259

Device Name
Vesta RF Cannula

Indications for Use *(Describe)*
The Vesta RF Cannula, in combination with an RF generator and probe, are intended for use in radiofrequency (RF) heat lesion procedures for relief of pain.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Petitioner's Exhibit 1064
Avanos v. Stratus
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510(k) Summary (21 CFR 807.92)

I. SUBMITTER

Submitter Name:	Biomerics
Address:	6030 West Harold Gatty Drive Salt Lake City, UT 84116
Telephone:	801-355-2705
Fax:	801-355-3045
Contact Person:	Jake Wakley
Email of Contact:	jwakley@biomerics.com
Date Prepared:	**01/24/2020**

II. DEVICE

Device Name:	Vesta RF Cannula
Common/Usual Name:	Cannula, Radiofrequency Lesion
Classification Name:	Radiofrequency Lesion Probe
Classification Panel:	Neurology
Regulation Device Name:	Radiofrequency Lesion Probe
Regulation Number:	21 CFR 882.4725
Regulatory Class:	2
Product Code:	GXI

III. PREDICATE DEVICE

Predicate Name:	Nimbus Electrosurgical Radiofrequency Multitined Expandable Electrode
Common/Usual Name:	Probe, Radiofrequency Lesion
Classification Name:	GXI – Radiofrequency Lesion Probe
Premarket Notification:	K121773
Manufacturer:	Biomerics

Per the FDA Medical Device Recalls Database, this predicate has not been subject to a design related recall.

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IV. DEVICE DESCRIPTION

The Vesta RF Cannula consists of an insulated cannula with an active tip for use in radiofrequency heat lesion procedures for the relief of pain. It is designed to be used with compatible pain management generators and probes that have a maximum voltage rating less than or equal to 280 V. The Vesta RF Cannula is sterilized and intended for single use only.

V. INDICATIONS FOR USE

The Vesta RF Cannula, in combination with an RF generator and probe, are intended for use in radiofrequency (RF) heat lesion procedures for relief of pain.

VI. COMPARISION OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Vesta RF Cannula device is substantially equivalent to the predicate device, the Nimbus Electrosurgical Radiofrequency Multitined Expandable Electrode. Both the subject and the predicate device consist of an insulated cannula with an active tip that directs RF energy into target tissues. Both are intended for use in radiofrequency (RF) heat lesion procedures for relief of pain. Both have the same intended use, indications for use, similar design, similar sizes, similar or the same materials and similar properties. See comparison table below.

Attribute	Predicate Device	Subject Device	
Device Name	Nimbus Electrosurgical Radiofrequency Multitined Expandable Electrode	Vesta RF Cannula	Substantially Equivalent or Identical to Predicate
510(k) Number	K121773	K190259 (Pending)	N/A
510(k) Submitter	Biomerics	Biomerics	Identical to Predicate
Trade Name	Nimbus Electrosurgical Radiofrequency Multitined Expandable Electrode	Vesta RF Cannula	Substantially Equivalent to Predicate
Classification Name	Probe, Radiofrequency Lesion	Probe, Radiofrequency Lesion	Identical to Predicate
Regulatory Class	2	2	Identical to Predicate
Classification Regulation	21 CFR 882.4725	21 CFR 882.4725	Identical to Predicate

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Attribute	Predicate Device	Subject Device	
Device Name	Nimbus Electrosurgical Radiofrequency Multitined Expandable Electrode	Vesta RF Cannula	Substantially Equivalent or Identical to Predicate
Product Code	GXI	GXI	Identical to Predicate
Review Panel / Division	Neurology	Neurology	Identical to Predicate
Variants	• NIM-050-10BB • NIM-100-10BB • NIM-150-10BB • NIM-100-10BB-CS	• NLT-100-22-10-BB • NLT-100-22-05-BB • NLT-100-22-10-CS • NLT-150-22-10-BB • NLT-150-22-10-CS • NLT-50-22-10-BB • NLT-100-20-10-BB • NLT-100-20-10-CS • NLT-100-20-10-CH • NLT-150-20-10-BB • NLT-150-20-10-CS • NLT-100-18-10-BB • NLT-100-18-10-CS • NLT-150-18-10-BB • NLT-150-18-10-CS • NLT-100-18-10-CH • NLT-150-20-10-CH • NLT-150-18-10-CH • NLT-100-22-10-CH • NLT-150-22-10-CH	Substantially Equivalent to Predicate
Intended Use	Intended for use in radiofrequency (RF) heat lesion procedures for relief of pain.	Intended for use in radiofrequency (RF) heat lesion procedures for relief of pain.	Identical to Predicate (The Intended Use has not changed as a result of the Modifications)

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Attribute	Predicate Device	Subject Device	
Device Name	Nimbus Electrosurgical Radiofrequency Multitined Expandable Electrode	Vesta RF Cannula	Substantially Equivalent or Identical to Predicate
Indications for Use	The Nimbus Electrosurgical Radiofrequency Multitined Expandable Electrode, in combination with an RF generator and probe, are intended for use in radiofrequency (RF) heat lesion procedures for relief of pain.	The Vesta RF Cannula, in combination with an RF generator and probe, are intended for use in radiofrequency (RF) heat lesion procedures for relief of pain.	Identical to Predicate
Clinical Mechanism of Action	Insulated cannula with an active tip that directs RF energy into target tissue.	Insulated cannula with an active tip that directs RF energy into target tissue.	Identical to Predicate
Anatomical Sites	Necrosis of soft tissues	Necrosis of soft tissues	Identical to Predicate
Where Used	Hospital, Surgical Suite	Hospital, Surgical Suite	Identical to Predicate
Active Tip	Deployable tines to modify the shape of the lesion.	Multiple active tip lengths available.	Substantially Equivalent to Predicate
Specific Drug Use	None	None	Identical to Predicate
Human Factors	Restricted to use by physicians familiar with radio-frequency lesion techniques.	Restricted to use by physicians familiar with radio-frequency lesion techniques.	Identical to Predicate
Standards Met	• ASTM D4169-16 • AAMI TIR28 • BS EN 15223-1 • IEC 60601-2-2 • ISO 7864 • ISO 10993-1 • ISO 10993-5 • ISO 10993-7 • ISO 10993-10 • ISO 11135 • ISO 11607-1	• IEC 60601-2-2 • ISO 7864 • ISO 9626 • ISO 10993-1 • ISO 10993-5 • ISO 10993-7 • ISO 10993-10 • ISO 11135 • ISO 11607-1 • ISO 13485 • ISO 14971	Substantially Equivalent to Predicate

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Attribute	Predicate Device	Subject Device	
Device Name	Nimbus Electrosurgical Radiofrequency Multitined Expandable Electrode	Vesta RF Cannula	Substantially Equivalent or Identical to Predicate
	• ISO 11607-2 • ISO 13485 • ISO 14971 • ISO 80369-7	• ISO 15223-1 • ISO 80369-7 • ISTA 2A	
Physical Description (Diameter, Length, etc.)	Diameter: 17G Length: ≤15cm Active Length: 4-10mm	Diameter: 18-22G Length: ≤15cm Active Length: 5-10mm	Substantially Equivalent to Predicate
Components / Materials	Hubs: Thermoplastics Cannula/Needle: Stainless steel with polymer insulation Tines: Stainless Steel	Hubs: Thermoplastics Cannula/Needle: Stainless steel with polymer insulation	Substantially Equivalent to Predicate
General Materials	Biocompatible (Polyethylene, Polycarbonate, Stainless Steel, Nylon, Silicone and Polyethylene Terephthalate (PET), Biocompatible Colorants)	Biocompatible (Polycarbonate, Stainless Steel, and Polyethylene Terephthalate (PET), & Biocompatible Colorants)	Substantially Equivalent to Predicate
Insulation	IEC 60601 compliant PET to protect user and patient from errant electrical discharge.	IEC 60601 compliant PET to protect user and patient from errant electrical discharge.	Substantially Equivalent to Predicate
Electrical Safety	Conforms to IEC 60601-2-2	Conforms to IEC 60601-2-2	Identical to Predicate
Single-Use	Yes	Yes	Identical to Predicate
Sterilization	EtO	EtO	Identical to Predicate

Table 1: Technological Characteristics with the Predicate Device

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VII. PERFORMANCE DATA

Bench Testing

Bench tests are listed below in Table 2.

Standard	Test Name	Result
ISO 6009	Needle Diameter	Passed
ISO 9626	Cannula Verification	Passed
ISO 7864	Needle Tip Inspection	Passed
ISO 80369-7	Luer Acceptance	Passed
ISO 15223-1	Label Proof Approval	Passed
ISO 11135, ISO 10993-7, ISO 11138-2	Sterilization Assessment	Passed
ISO 11607-1	Stability and Aging Assessment	Passed

Table 2: Vesta RF Cannula Bench Testing

Clinical Testing

No clinical testing was performed.

Biocompatibility

All Vesta RF Cannula subject devices tested for biocompatibility were the same configuration: 150mm length, 18G diameter, 10mm active tip, with both green and blue hub variants either pooled or tested separately. The subject device was evaluated per ISO 10993 as a limited contact device (≤24 hours), and was found to be biocompatible for its intended use. The subject device is therefore equivalent to the predicate device.

Test	Result	Conclusions
Irritation – Intracutaneous Injection (Pooled Blue/Green Hub)	The test article sites did not show a significantly greater biological reaction than the sites injected with the control article.	Non-irritant
Sensitization – Kligman Maximization (Pooled Blue/Green Hub)	The USP 0.9% Sodium Chloride for Injection (NaCl) and Cottonseed Oil (CSO) extracts of the test article, NLT-150-18-10-CS Blue Hub Lot 18121-1 NLT-150-18-10-CS Green Hub lot 18121·1, elicited no reaction at the challenge (0% sensitization), following an induction phase.	Non-sensitizer
Cytotoxicity – MEM Elution (Blue Hub)	Cell monolayers treated with test sample exhibited no reactivity (Grade 0).	Non-cytotoxic
Cytotoxicity – MEM Elution (Green Hub)	Cell monolayers treated with test sample exhibited no reactivity (Grade 0).	Non-cytotoxic

Test	Result	Conclusions
Systemic Toxicity (Blue Hub)	None of the test article treated animals were observed with clinical signs consistent with toxicity at any of the observation periods.	Non-toxic
Systemic Toxicity (Green Hub)	None of the test article treated animals were observed with clinical signs consistent with toxicity at any of the observation periods.	Non-toxic
EO Residuals	EO and ECH residuals were tested per *ISO 10993-7 Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals* and were below allowable limits established in Section 4.3 for a limited exposure device (≤24 hours).	EO sterilization is appropriate for the subject device
Material Mediated Pyrogen	The material-mediated pyrogenicity risk of the Vesta RF Cannula was assessed and was found to be acceptable	Non-pyrogenic

Table 3: Vesta RF Cannula Biocompatibility Testing

VIII. CONCLUSION

Through performance bench testing results, it has been demonstrated that the subject device is substantially equivalent to the predicate device, Nimbus Electrosurgical Radiofrequency Multitined Expandable Electrode, K121773.