

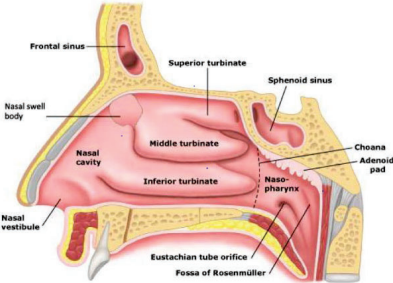
Exhibit W

EXHIBIT W—U.S. Patent No. 10,894,011

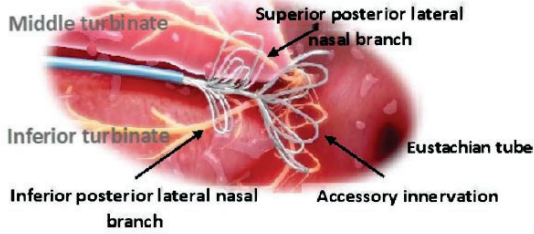
Claims of USP 10,894,011	Neuromark system
1. Apparatus for treatment of a nasal condition by altering function of a nasopharyngeal passage of a patient, the apparatus comprising:	• The Neuromark system treats chronic rhinitis, which is a nasal condition, by altering the function of a nasopharyngeal passage, such as by reducing mucus secretion and/or disrupting nerves. • The Neuromark system’s indications for use is for treating “chronic rhinitis.” INDICATIONS FOR USE: The NEUROMARK® System is indicated for use in otorhinolaryngology (ENT) surgery for creation of radiofrequency (RF) lesions to disrupt posterior nasal nerves in patients with chronic rhinitis. Ex. R (Neurent Brochure, NEUROMARK, Rhinitis Neurolysis Therapy, Posterior Nerves Matter) at 3. DEVICE DESCRIPTION The NEUROMARK® System is intended for the application of Radiofrequency (RF) energy to create lesions in mucosal tissue in otolaryngological [also known as Ear, Nose and Throat (ENT)] procedures in patients with chronic rhinitis. The NEUROMARK® System is composed of: 1. The NEUROMARK® Device and 2. The NEUROMARK® Radiofrequency (RF) Console Ex. K (Instructions for Use, NEUROMARK® System) at 1. The NEUROMARK™ System is indicated for use in otorhinolaryngology (ENT) surgery for creation of radiofrequency (RF) lesions to disrupt posterior nasal nerves in patients with chronic rhinitis. Ex. H (Letter from FDA dated Oct. 22, 2021 to Kenny Walsh of Neurent Medical, Galway Ireland, regarding Section 510(k) premarket notification for the Neuromark system) at 2. The NEUROMARK® System is indicated for use in otorhinolaryngology (ENT) surgery for creation of radiofrequency (RF) lesions to disrupt posterior nasal nerves in patients with chronic rhinitis.

Claims of USP 10,894,011	Neuromark system
	Ex. I (Letter from FDA dated Oct. 26, 2022 to Karen Peterson of Neurent Medical, Galway Ireland, regarding Section 510(k) premarket notification for the Neuromark system) at 3. - Neurent funded studies to show that the Neuromark system “provides safe and effective treatment to the posterior nasal nerves for patients with chronic rhinitis.” Conclusions: The NEUROMARK System is a novel radiofrequency ablation device that provides safe and effective treatment to the posterior nasal nerves for patients with chronic rhinitis. Study participants experienced statistically significant and clini- Ex. S (“Clinical evaluation of a novel multipoint radiofrequency ablation device to treat chronic rhinitis,” Douglas D. Reh, MD et al., Laryngoscope Investigative Otolaryngology, 8:367-372 (2023)) at 367. - Neurent explains that “chronic rhinitis may be caused by abnormal or overactive posterior nasal nerves,” which “can cause mucus creation to go into overdrive creating a near-constant runny, stuffy nose and/or post-nasal drip.” Ex. R at 4. Use of the Neuromark system is intended provide relief from the “core symptoms,” including relief from runny noses due to mucus production. Ex. R at 3, 4. For many patients, chronic rhinitis may be caused by abnormal or overactive posterior nasal nerves in the nose. Those nerve signals can cause mucus creation to go into overdrive, creating a near-constant runny, stuffy nose and/or post-nasal drip. Ex. R at 4. While not life-threatening, chronic rhinitis can seriously impact your quality of life. Sufferers feel dependent on medications that often only deliver temporary relief¹, or they rely on tissues or sprays to keep up with a constant runny and/or stuffy nose. Worst of all, many people feel annoyance or embarrassment in public because of their symptoms, preventing them from living life to the fullest. Ex. R at 4.

Claims of USP 10,894,011	Neuromark system
a hand-held elongate body having proximal and distal portions, the distal portion being configured for positioning in a nasopharyngeal passage of a patient with the proximal portion positioned outside the nasopharyngeal passage;	• The Neuromark system includes the Neuromark Device and Neuromark Generator. Ex. H at 4; Ex. I at 4. The Neuromark Device includes a hand-held elongate body having proximal and distal portions, the distal portion being configured for positioning in the nasopharyngeal passage of a patient with the proximal portion positioned outside the nasopharyngeal passage. • As shown below, the Neuromark Device is a hand-held device with an elongate body and has a proximal portion and a distal end with an end effector. End Effector proximal stage End Effector distal stage Figure 2: NEUROMARK Device Ex. Q (NEUROMARK® System Mechanism of Action) at 3. The device is a hand-held, single-use, low-power, bipolar radiofrequency device with an electrode array (end effector) at the device tip (Figure 2). The end effector consists of multiple leaflets, each of which contain several bipolar electrode pairs allowing for the creation of several discrete ablation sites. The end effector has a proximal stage and a distal stage. This design is intentional to allow flexibility, conformity to patient's anatomy, and to allow RF ablation sites to be created in nerve-rich areas of the lateral wall. Ex. Q at 3.

Claims of USP 10,894,011	Neuromark system
	- The Neuromark Device is “introduced into the nasal cavity and advanced to the posterior recesses of the inferior/middle/superior meatus” and the “distal stage of the end effector is places in the nasal choanae (posterior to the lateral attachment of the middle turbinate), while the proximal stage is placed in the middle meatus region.” Ex. Q at 3. Under endoscopic guidance, the device is introduced into the nasal cavity and advanced to the posterior recesses of the inferior/ middle/superior meatus. The distal stage of the end effector is placed in the nasal choanae (posterior to the lateral attachment of the middle turbinate), while the proximal stage is placed in the middle meatus region. Figure 3 illustrates proper positioning and deployment of the end effector to maximize nerve disruption potential. Ex. Q at 3. - An example of the nasal cavity showing the nasopharynx and choana is shown below.  www.bergerhenryent.com/nasal-swell-bodies/.

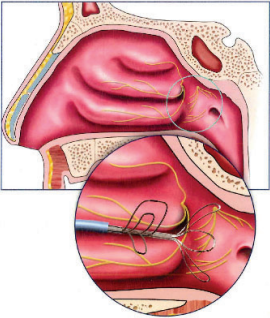
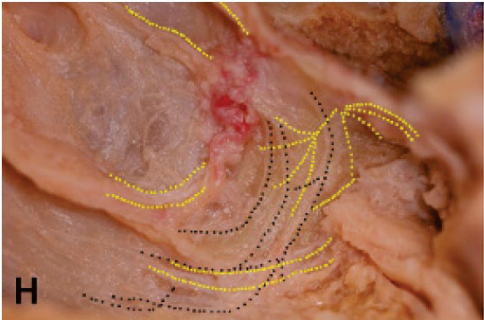
Claims of USP 10,894,011	Neuromark system
	Neurent repeatedly demonstrates in its documentation for the Neuromark system and its literature that the distal end of the Neuromark Device is configured for positioning in a nasopharyngeal passage of a patient while the proximal portion is positioned outside the nasopharyngeal passage. Figure 3: NEUROMARK Device with deployed end effector accommodating the area of the posterior nasal nerves. Ex. Q at 3. 8. Under endoscopic guidance, align the inter stage marker on the shaft to the lateral attachment of the middle turbinate. This provides an approximation of the gap between the distal and proximal end effector leaflets to aid positioning. Ex. K at 3.

Claims of USP 10,894,011	Neuromark system
	10. Make any necessary minor adjustments to ensure that the device is positioned in the correct anatomical position. Verify the correct position endoscopically. CAUTION: Ensure that the proximal end of the end effector wraps around the middle turbinate anterior to the attachment of the turbinate to the lateral wall. NOTE: The end effector consists of a distal and proximal stage. The leaflets are super elastic and spring out to enforce mucosal apposition on the lateral wall. The multi-stage elastic leaflet set-up accommodates the area of the posterior nasal nerves. Ex. K at 3.  FIGURE 2 The NEUROMARK positioning. Ex. S at 369.
an energy transmission element in the distal portion configured to deliver energy to target tissue in the nasopharyngeal passage; and	• The Neuromark system includes the Neuromark Device and Neuromark Generator. Ex. H at 4. The Neuromark Device includes an energy transmission element in the distal portion configured to deliver energy to target tissue in the nasopharyngeal passage. • The Neuromark Device has an end effector at the distal end.

Claims of USP 10,894,011	Neuromark system
	Ex. Q at 3. • The end effector has “multiple leaflets, each of which contain several bipolar electrode pairs” and deliver radiofrequency energy. Ex. Q at 3. The device is a hand-held, single-use, low-power, bipolar radiofrequency device with an electrode array (end effector) at the device tip (Figure 2). The end effector consists of multiple leaflets, each of which contain several bipolar electrode pairs allowing for the creation of several discrete ablation sites. Ex. Q at 3. • According to Neurent’s Instructions for Use for the Neuromark system, the distal portion of the Neuromark device has numerous bipolar electrodes for delivering radiofrequency energy. NEUROMARK® Device The NEUROMARK® Device is a hand-held, single-use, bipolar radiofrequency device which comprises a handle, shaft and treatment tip. The treatment tip, which is referred to as the end effector, consists of an array of bipolar electrodes that deliver bipolar RF energy while monitoring feedback on tissue bio-impedance changes allowing for controlled RF energy delivery. The shaft of the device is pre-shaped to aid access and delivery to the nasal cavity but is malleable to allow the user to bend or shape the shaft to accommodate variations in anatomy to access the desired treatment area. Ex. K at 1.

Claims of USP 10,894,011	Neuromark system
	- Neurent's 510(k) states that the Neuromark Device applies "radiofrequency energy to create lesions in tissue by coagulation necrosis" and "disrupt the posterior nasal nerves." Ex. H at 3, 4. Application of radiofrequency energy to create lesions in tissue by coagulation necrosis is the technological principle for both the subject and predicate devices. This is based on the use of a surface contacting electrode array device, connected to an RF generator to apply RF energy to mucosal tissue. At a high level, the NEUROMARK™ and the predicate have the following same Ex. H at 4. The NEUROMARK® System is indicated for use in otorhinolaryngology (ENT) surgery for creation of radiofrequency (RF) lesions to disrupt posterior nasal nerves in patients with chronic rhinitis. Ex. H at 3. - Neurent repeatedly demonstrates in its documentation for the Neuromark system and its literature that the Neuromark Device is configured to deliver energy to target tissue in the nasopharyngeal passage. Under endoscopic guidance, the device is introduced into the nasal cavity and advanced to the posterior recesses of the inferior/middle/superior meatus. The distal stage of the end effector is placed in the nasal choanae (posterior to the lateral attachment of the middle turbinate), while the proximal stage is placed in the middle meatus region. Figure 3 illustrates proper positioning and deployment of the end effector to maximize nerve disruption potential. Ex. Q at 3.

Claims of USP 10,894,011	Neuromark system
	Figure 3: NEUROMARK Device with deployed end effector accommodating the area of the posterior nasal nerves. Ex. Q at 3. FIGURE 2 The NEUROMARK positioning. Ex. S at 369. itations. The device comprises a two-stage design, where proximal and distal flexible leaflets conform to patient anatomy, maximizing access to nerve-rich areas on the lateral wall of the nasal cavity, and allowing more posterior placement than the other available devices. Ex. S at 368.

Claims of USP 10,894,011	Neuromark system
	The Underlying Cause Disruption of the parasympathetic nerves to the lateral nasal wall has been proven to reduce both congestion and rhinorrhea in Rhinitis patients. Research has shown that the inflammatory process of the nasal mucosa is driven by branches of the parasympathetic nerves embedded in tissues of the inferior turbinate and the lateral nasal wall. This is the motor supply of the inflammatory cascade, controlling the signalling function and the resulting physiological effects of the sub-mucosal glands (rhinorrhea) and venous sinuses (congestion) within the nasal tissue.¹  <u>Go Beyond.</u> Ex. R at 1.  Figure 1: The nerves penetrating vertical plate of the palatine bone and innervating nasal lateral wall. Yellow dotted lines indicate the nerve fibres in the superficial layer and black dotted lines indicate the nerve fibres in the deep layer [8]. Ex. Q at 2.

Claims of USP 10,894,011	Neuromark system
	8. Under endoscopic guidance, align the inter stage marker on the shaft to the lateral attachment of the middle turbinate. <i>This provides an approximation of the gap between the distal and proximal end effector leaflets to aid positioning.</i>  Ex. K at 3. 10. Make any necessary minor adjustments to ensure that the device is positioned in the correct anatomical position. Verify the correct position endoscopically. CAUTION: Ensure that the proximal end of the end effector wraps around the middle turbinate anterior to the attachment of the turbinate to the lateral wall. NOTE: The end effector consists of a distal and proximal stage. The leaflets are super elastic and spring out to enforce mucosal apposition on the lateral wall. The multi-stage elastic leaflet set-up accommodates the area of the posterior nasal nerves.  Ex. K at 3.
an energy source operatively coupled to the energy transmission element for supplying energy thereto according to one or more parameters selected so as to alter nasopharyngeal cells in the target tissue such that nasal congestion is reduced.	• The Neuromark Device delivers energy to the target tissue so as to alter nasopharyngeal tissue cells, including ablating and dissecting tissue and/or creating lesions in the tissue to reduce nasal congestion. • Neurent's 510(k) states that the Neuromark applies "radiofrequency energy to create lesions in tissue by coagulation necrosis." Application of radiofrequency energy to create lesions in tissue by coagulation necrosis is the technological principle for both the subject and predicate devices. This is based on the use of a surface contacting electrode array device, connected to an RF generator to apply RF energy to mucosal tissue. At a high level, the NEUROMARK™ and the predicate have the following same Ex. H at 5.

Claims of USP 10,894,011	Neuromark system
	The NEUROMARK® System is indicated for use in otorhinolaryngology (ENT) surgery for creation of radiofrequency (RF) lesions to disrupt posterior nasal nerves in patients with chronic rhinitis. Ex. I at 3. - Neurent’s Instructions for Use for the Neuromark system states that the system applies RF energy to create lesions in mucosal tissue. DEVICE DESCRIPTION The NEUROMARK® System is intended for the application of Radiofrequency (RF) energy to create lesions in mucosal tissue in otolaryngological [also known as Ear, Nose and Throat (ENT)] procedures in patients with chronic rhinitis. The NEUROMARK® System is composed of: 1. The NEUROMARK® Device and 2. The NEUROMARK® Radiofrequency (RF) Console Ex. K at 1. - Brian Shields, Neurent’s founder and CEO has confirmed that the Neuromark system creates numerous micro-lesions in the tissue. The unique therapy wand comprises of a super-elastic leaflet design that conforms to highly varying anatomy and disrupts multiple primary and accessory parasympathetic nerve branches with a single placement. The smart console guides optimal placement of the leaflets and provides visual cues on the treatment status. The therapy leaflets simultaneously deliver numerous micro-lesions to disrupt multiple nerve segments with a single placement. Our approach differs from other devices Ex. N (Medgadget, “In-Office Treatment for Chronic Rhinitis: Interview with Brian Shields, Neurent Medical CEO,” (Feb. 3, 2021)) at 8. - Neurent acknowledges in marketing literature that the delivery of RF energy alters tissue cells, stating that “[a]s tissue properties change due to the thermal effects from RF energy, conductivity increases and bioimpedance at the electrode-tissue interface falls.” Ex. Q at 3.

Claims of USP 10,894,011	Neuromark system
	body, or other biomaterial such as nasal tissue, impedes electric current flow [11]. As tissue properties change due to the thermal effects from RF energy, conductivity increases and bioimpedance at the electrode-tissue interface falls; conversely, as tissue conductivity drops, bioimpedance at the electrode-tissue interface rises. The depth of nasal mucosal tissue varies between patients and within each patient's nasal cavity. By using bioimpedance control, the NEUROMARK System can adjust for local tissue conditions, altering energy delivery time depending on the detected tissue state. Ex. Q at 3. • According to Neurent, the Neuromark system reduces the symptoms of chronic rhinitis, including reducing congestion. Neurent explains that “chronic rhinitis may be caused by abnormal or overactive posterior nasal nerves,” which “can cause mucus creation to go into overdrive creating a near-constant runny, stuffy nose and/or post-nasal drip.” Ex. R at 4. Use of the Neuromark system is intended provide relief from the “core symptoms,” including relief from congestion. Ex. R at 3, 4. For many patients, chronic rhinitis may be caused by abnormal or overactive posterior nasal nerves in the nose. Those nerve signals can cause mucus creation to go into overdrive, creating a near-constant runny, stuffy nose and/or post-nasal drip. Ex. R. at 4.

Claims of USP 10,894,011	Neuromark system
	While not life-threatening, chronic rhinitis can seriously impact your quality of life. Sufferers feel dependent on medications that often only deliver temporary relief¹, or they rely on tissues or sprays to keep up with a constant runny and/or stuffy nose. Worst of all, many people feel annoyance or embarrassment in public because of their symptoms, preventing them from living life to the fullest. Ex. R at 4. The NEUROMARK device disrupts the nerves and may reduce core symptoms. Ex. R at 3. • Neurent founder and CEO Brian Shields has explained that using the Neuromark device as intended and instructed by placing the end effector by the target tissue and delivering therapy “disrupts multiple primary and accessory parasympathetic nerve branches with a single placement,” which reduces “the core symptoms of congestion and rhinorrhea.” Ex. N at 6, 8. The unique therapy wand comprises of a super-elastic leaflet design that conforms to highly varying anatomy and disrupts multiple primary and accessory parasympathetic nerve branches with a single placement. The smart console guides optimal placement of the leaflets and provides visual cues on the treatment status. The therapy leaflets simultaneously deliver numerous micro-lesions to disrupt multiple nerve segments with a single placement. Our approach differs from other devices Ex. N at 8. Brian Shields: NEUROMARK RNT is an innovative in-office treatment option for chronic allergic and non-allergic rhinitis. It's designed to disrupt hard-to-reach, hyperactive parasympathetic nerves that drive the core symptoms of congestion and rhinorrhea, while maintaining the integrity of adjacent nasal tissue. Ex. N at 6

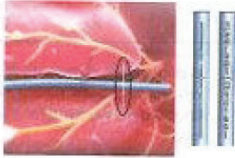
Claims of USP 10,894,011	Neuromark system
	• According to Neurent, the Neuromark system is used to reduce the symptoms of chronic rhinitis, including reducing nasal congestion and postnasal drip significantly. And Neurent funded the Clarity study to demonstrate that using the Neuromark Device and system as instructed by Neurent significantly reduces congestion and post-nasal drip thus reducing mucus secretion. All enrolled participants underwent bilateral posterior nasal nerve disruption with the NEUROMARK System (Figure 1) under local anesthesia in an office setting. The type of local anesthesia was individualized based on the performing surgeon's preference. The device uses a proprietary algorithm to deliver controlled RF energy to create microlesions at the target site while minimizing collateral injury. An array of distal and proximal electrode leaflets simultaneously creates up to 20 ablation sites at the posterior lateral nasal nerves and accessory parasympathetic nerves from the pterygopalatine ganglion (Figure 2). Impedance thresholds are monitored individually for each leaflet, ensuring treatment is delivered adequately to the intended tissue and also discontinued at the optimal time. Ex. S at 368. Rhinorrhea, nasal congestion, nasal itching, sneezing, and postnasal drip domains of the VAS NSS all demonstrated significant improvement at 1 and 3 months compared with baseline (all $p < .001$) (Table 2). While all symptoms improved, the greatest changes were seen in rhinorrhea, nasal congestion, and postnasal drip ($p < .0001$). Ex. S at 369.

Claims of USP 10,894,011	Neuromark system
	Neurent even issued a press release touting the Clarity study as demonstrating that the Neuromark device when used as Neurent instructs “demonstrated significant improvement in rhinorrhea and nasal congestion symptoms at 3 months” and “statistically significant and clinically meaningful improvement in symptoms and quality of life assessments at 3 months post NEUROMARK procedure.” Ex. P (Press Release: New Data Show NEUROMARK® Chronic Rhinitis Treatment Offers Significant Symptom Improvements, Mar. 21, 2023).
2. The apparatus of claim 1, wherein the energy transmission element comprises at least one electrode.	- The energy transmission element on the end effector at the distal portion of the Neuromark device has numerous bipolar electrodes for delivering radiofrequency energy. NEUROMARK® Device The NEUROMARK® Device is a hand-held, single-use, bipolar radiofrequency device which comprises a handle, shaft and treatment tip. The treatment tip, which is referred to as the end effector, consists of an array of bipolar electrodes that deliver bipolar RF energy while monitoring feedback on tissue bio-impedance changes allowing for controlled RF energy delivery. The shaft of the device is pre-shaped to aid access and delivery to the nasal cavity but is malleable to allow the user to bend or shape the shaft to accommodate variations in anatomy to access the desired treatment area. Ex. K at 1. - Neurent literature confirms that the Neuromark system includes a device that is a “bipolar radiofrequency device with an electrode array (end effector) at the device tip” and includes leaflets “which contain several bipolar electrode pairs.” The diagram shows a hand-held device with a handle, a long shaft, and a treatment tip. The handle has a control knob and a power button. The shaft is labeled 'End Effector proximal stage'. The treatment tip is labeled 'End Effector distal stage' and shows an array of bipolar electrodes.

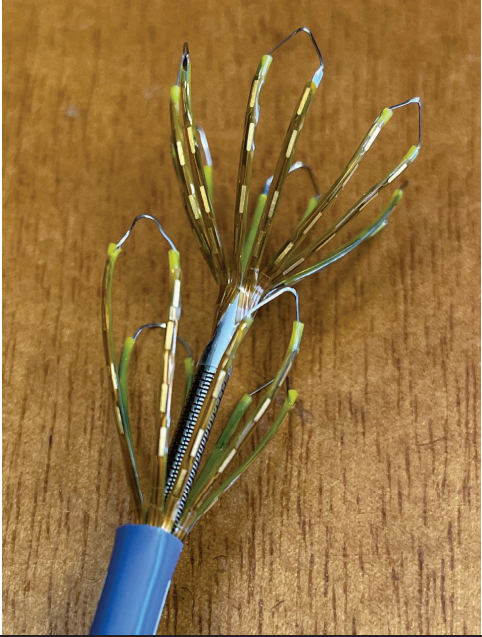
Claims of USP 10,894,011	Neuromark system
	The device is a hand-held, single-use, low-power, bipolar radiofrequency device with an electrode array (end effector) at the device tip (Figure 2). The end effector consists of multiple leaflets, each of which contain several bipolar electrode pairs allowing for the creation of several discrete ablation sites. Ex. Q at 3. In submissions to the FDA, Neurent explained that Neuromark system has “an array of bipolar micro electrodes” and that “[t]hese electrodes deliver bipolar RF energy.” The NEUROMARK™ Device is a hand-held single-use bi-polar radiofrequency device which comprises a handle, shaft, and treatment tip. The treatment tip, which is referred to as the End Effector, consists of an array of bipolar micro electrodes. These electrodes deliver bipolar RF energy while monitoring feedback on the tissue bio-impedance changes allowing for controlled RF energy level delivery. The shaft of the device is pre-shaped for optimal access and delivery to the nasal cavity but is malleable to allow the user to bend or shape the shaft to accommodate variations in anatomy to access the desired treatment area(s). The NEUROMARK™ Device is operated via Ex. H at 4-5. The NEUROMARK® Device is a hand-held, single-use, bipolar radiofrequency device which comprises a handle, shaft, and treatment tip. The treatment tip, which is referred to as the End Effector, consists of an array of bipolar electrodes that deliver RF energy while monitoring feedback on tissue bio-impedance changes allowing for controlled RF energy delivery. The shaft Ex. I at 4.
5. The apparatus of claim 1, wherein the energy supplying means comprises an RF generator.	The Neuromark system delivers RF energy through the electrodes on the end effector, and the energy is supplied by an RF generator. Neurent’s 510(k) submissions state that

Claims of USP 10,894,011	Neuromark system
	the “NEUROMARK® System is composed of the NEUROMARK® Device and the NEUROMARK® Radiofrequency (RF) Console.” Ex. I at 4; <i>see also</i> Ex. H at 4. • Neurent also explain in the Instructions for Use that the Neuromark system include an RF generator. DEVICE DESCRIPTION The NEUROMARK® System is intended for the application of Radiofrequency (RF) energy to create lesions in mucosal tissue in otolaryngological [also known as Ear, Nose and Throat (ENT)] procedures in patients with chronic rhinitis. The NEUROMARK® System is composed of: 1. The NEUROMARK® Device and 2. The NEUROMARK® Radiofrequency (RF) Console Ex. K at 1. • Neurent explains in the Instructions for Use for the “NEUROMARK Generator” that the Neuromark RF Console is an RF generator for delivering “RF energy to soft mucosal tissue.” INTENDED USE The NEUROMARK Generator is a bipolar radiofrequency (RF) platform intended for connection to the NEUROMARK Device to form the NEUROMARK System. The NEUROMARK System will deliver RF energy to soft mucosal tissue in otolaryngological / ENT procedures. Ex. L (NEURENT Medical, NEUROMARK Generator, Instructions for Use) at 2. The NEUROMARK System is a low-power bipolar RF system that targets nerve dense regions of the nasal cavity for disruption of the neural signals. Ex. Q at 4.

Claims of USP 10,894,011	Neuromark system
8. The apparatus of claim 1, wherein the energy transmission element is movable relative to the distal portion of the body.	- The Neuromark Device has an outer sheath that is retracted once the end effector is place in the desired position. Ex. K at 1. Once the sheath is retracted, the leaflets on the end effector move outwardly and are deployed. Ex. K at 1 The NEUROMARK® Device is operated via handle, slider and activation button. Once in the desired position within the nasal cavity, the operator moves the slider backwards which retracts the outer sheath, deploying the end effector. Using the activation button, the user initiates a bio-impedance check to assess and confirm contact between the end effector and the treatment area. Once the System confirms contact has been achieved, a subsequent press of the activation button initiates the RF energy delivery cycle. Ex. K at 1; <i>see also</i> Ex. H at 4; Ex. I at 4. - Neurent explains in the Instructions for Use that the “leaflets are super elastic and spring out to enforce mucosal apposition on the lateral wall,” showing that the energy transmission element is movable relative to the distal portion of the body. Ex. K at 3. 10. Make any necessary minor adjustments to ensure that the device is positioned in the correct anatomical position. Verify the correct position endoscopically. CAUTION: Ensure that the proximal end of the end effector wraps around the middle turbinate anterior to the attachment of the turbinate to the lateral wall. NOTE: The end effector consists of a distal and proximal stage. The leaflets are super elastic and spring out to enforce mucosal apposition on the lateral wall. The multi-stage elastic leaflet set-up accommodates the area of the posterior nasal nerves. An endoscopic image showing the distal portion of the Neuromark device inserted into the nasal cavity. The device's end effector is visible, with its leaflets extended towards the lateral wall of the nasal cavity. The surrounding tissue is pink and moist. Ex. K at 3.
9. The apparatus of claim 8, wherein the energy transmission	The Neuromark Device is designed to concentrate energy from the end effector laterally relative to the distal portion of the body.

Claims of USP 10,894,011	Neuromark system
element is configured to deliver energy laterally relative to the distal portion of the body.	8. Under endoscopic guidance, align the inter stage marker on the shaft to the lateral attachment of the middle turbinate. <i>This provides an approximation of the gap between the distal and proximal end effector leaflets to aid positioning.</i>  Ex. K at 3. 10. Make any necessary minor adjustments to ensure that the device is positioned in the correct anatomical position. Verify the correct position endoscopically. CAUTION: Ensure that the proximal end of the end effector wraps around the middle turbinate anterior to the attachment of the turbinate to the lateral wall. NOTE: The end effector consists of a distal and proximal stage. The leaflets are super elastic and spring out to enforce mucosal apposition on the lateral wall. The multi-stage elastic leaflet set-up accommodates the area of the posterior nasal nerves.  Ex. K at 3. The Neuromark system is design to target the “lateral wall of the nasal cavity” with energy concentrated latterly in the distal end of the device. The NEUROMARK System mechanism of action is the disruption of posterior nasal nerves by creating multiple lesions (RF ablations sites) via the application of low-power bipolar RF energy to nerve-rich areas on the lateral wall of the nasal cavity. Ex. Q at 2.

Claims of USP 10,894,011	Neuromark system
	Figure 1: The nerves penetrating vertical plate of the palatine bone and innervating nasal lateral wall. Yellow dotted lines indicate the nerve fibres in the superficial layer and black dotted lines indicate the nerve fibres in the deep layer [8]. Ex. Q at 2. • The end effector of the Neuromark Device includes leaflets designed to deliver energy and maximize “access to near-rich areas on the lateral wall of the nasal cavity.” Ex. itations. The device comprises a two-stage design, where proximal and distal flexible leaflets conform to patient anatomy, maximizing access to nerve-rich areas on the lateral wall of the nasal cavity, and allowing more posterior placement than the other available devices. Ex. S at 368.
10. The apparatus of claim 9, wherein the energy transmission element is configured to extend laterally from the distal portion of the body.	• The end effector of Neuromark device has multiple electrodes disposed on a lateral side of the distal portion of the treatment device as the below photograph of the end effector shows.

Claims of USP 10,894,011	Neuromark system
	
12. The apparatus of claim 1, further comprising: a sensing element on the distal portion of the body.	• The Neuromark Device includes a sensing element on the distal portion of the body, including multiple sensing electrodes on the end effector. The electrodes on the end effector deliver RF energy and sense bioimpedance. • The electrodes on the Neuromark Device “deliver bipolar RF energy while monitoring feedback on the tissue bio-impedance changes allowing for controlled RF energy level delivery.” Ex. H at 5; <i>see also</i> Ex. I at 4 (describing Neuromark’s “array of bipolar electrodes that deliver RF energy while monitoring feedback on tissue bio-impedance changes allowing for controlled RF energy delivery”).

Claims of USP 10,894,011	Neuromark system
	• Neurent’s technical literature for the Neuromark system further explains that the Neuromark “system uses bioimpedance to monitor the state of the nasal tissue and control power delivery” and that “[t]issue bioimpedance is continuously monitored.” Ex. Q at 3.
14. The apparatus of claim 12, further comprising: a monitoring system operatively coupled to the sensing element for indicating a degree of treatment of the target tissue.	• The Neuromark Device includes multiple sensing on the end effector that measure bioimpedance, which the system monitors for indicating a degree of treatment of the target tissue. • The electrodes on the Neuromark Device “deliver[s] bipolar RF energy while monitoring feedback on the tissue bio-impedance changes allowing for controlled RF energy level delivery.” Ex. H at 5; <i>see also</i> Ex. I at 4 (describing Neuromark’s “array of bipolar electrodes that deliver RF energy while monitoring feedback on tissue bio-impedance changes allowing for controlled RF energy delivery”). • Neurent’s technical literature for the Neuromark system further explains that the Neuromark “system uses bioimpedance to monitor the state of the nasal tissue and control power delivery” and that “[t]issue bioimpedance is continuously monitored.” Ex. Q at 3. • Neurent’s cofounder and CEO, Brian Shields has confirmed that the Neuromark system monitors tissue parameters for indicating a degree of treatment of the target tissue. Brian Shields: RNT’s algorithms and biofeedback monitoring are core components of the technology’s ability to safely and precisely disrupt nerves that cause underlying inflammation. Our algorithms monitor tissue parameters and control the location and duration of energy delivered. This prevents over treatment and tissue damage, and it also prevents under treatment that leads to unaltered symptom-causing nerves. Ex. N at 8.