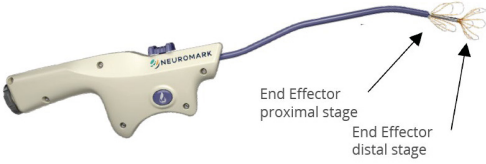
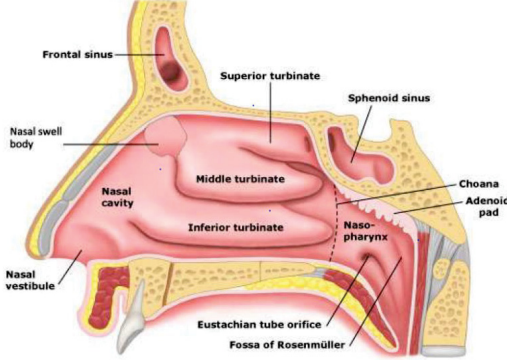


EXHIBIT V

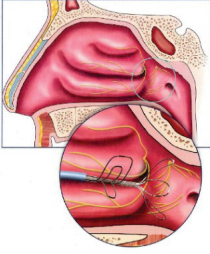
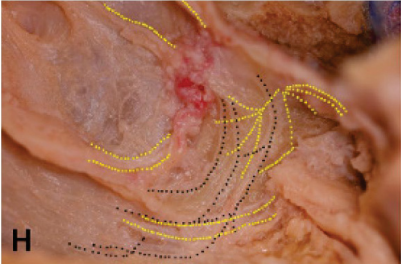
EXHIBIT V—U.S. Patent No. 10,610,675

Claims of USP 10,610,675	Neuromark system and method using Neuromark system
1. A method of treating a nasal condition of a patient comprising:	• The Neuromark system treats chronic rhinitis, which is a nasal condition. The Neurent instructs physicians to treat chronic rhinitis with the Neuromark system. • 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. 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.

Claims of USP 10,610,675	Neuromark system and method using Neuromark system
	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 clinical improvement in symptoms of chronic rhinitis. 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.
positioning a distal portion of a treatment device proximate to target tissue in a nasopharyngeal passage of a patient; and	- The Neuromark system includes the Neuromark Device and Neuromark Generator. Ex. H at 4; Ex. I at 4. The Neuromark Device is intended for use in the posterior nasal cavity to target tissue in the nasopharyngeal passage, and Neurent instructs physicians to position the distal portion/end effector of the Neuromark Device proximate to target tissue in the nasopharyngeal passage of a patient. - The Neuromark Device has an end effector at the distal end.  Ex. Q (NEUROMARK[®] System Mechanism of Action) at 3. - 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 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.” Ex. Q at 3.

Claims of USP 10,610,675	Neuromark system and method using Neuromark system
	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/.

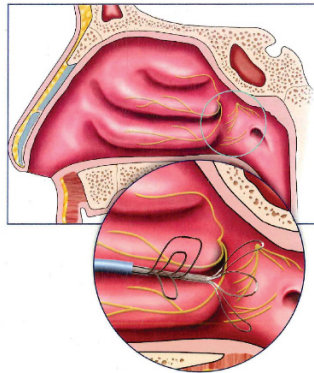
Claims of USP 10,610,675	Neuromark system and method using Neuromark system
	• Neurent repeatedly demonstrates placement of the distal portion of the Neuromark Device proximate to target tissue in a nasopharyngeal passage in its literature, including its Instructions for Use. Figure 3: NEUROMARK Device 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.

Claims of USP 10,610,675	Neuromark system and method using Neuromark system
	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. 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  Go Beyond. 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 10,610,675	Neuromark system and method using Neuromark system
	Neurent expressly instructs such placement in its Instruction for Use. 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.
administering therapy to the target tissue with the treatment device so as to disrupt neural activity such that mucus secretion is reduced in the nasopharyngeal passage;	The Neuromark system targets tissue to disrupt neural activity to reduce the symptoms of chronic rhinitis, including reducing mucus secretion in the nasopharyngeal passage as confirmed by Neurent's 510(k) submission, Instructions for Use, Clarity study, press releases, and other marketing material. Neurent instructs physicians to administer therapy to disrupt neural activity such that mucus secretion is reduced in the nasopharyngeal passage. 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 4.

Claims of USP 10,610,675	Neuromark system and method using 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 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 10,610,675	Neuromark system and method using Neuromark system
	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 (Medgadget, “In-Office Treatment for Chronic Rhinitis: Interview with Brian Shields, Neurent Medical CEO,” (Feb. 3, 2021)) 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. • Neurent confirms that the method of therapy provided by the Neuromark system disrupts neural activity.

Claims of USP 10,610,675	Neuromark system and method using 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 signaling 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. • Neurent instructs physicians to disrupt neural activity with the Neuromark system and physicians do that using local anesthesia to reduce the symptoms of chronic rhinitis, including reducing nasal congestion and postnasal drip significantly. And the Clarity study funded by Neurent reportedly demonstrated that using the Neuromark Device as instructed by Neurent significantly reduces congestion and post-nasal drip thus reducing mucus secretion.

Claims of USP 10,610,675	Neuromark system and method using Neuromark system
	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. • 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.”

Claims of USP 10,610,675	Neuromark system and method using Neuromark system
	"People living with chronic rhinitis have had limited options when traditional therapies fail. Other therapies on the market don't always adequately address symptoms for every patient," said Douglas D. Reh, MD, FARS, Otolaryngology Specialist at ENT Associates and the study's principal investigator. "The data showed 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).
wherein administering therapy comprises at least one of delivering energy to the target tissue and changing the temperature of the target tissue.	• The Neuromark Device delivers energy to the target tissue to cause ablation and dissection, which is caused by changing the temperature of the target tissue. Neurent instructs physicians to use the Neuromark Device to administer therapy by delivering energy to the target tissue and changing the temperature of the tissue. • Neurent's 510(k) states that the Neuromark system applies "radiofrequency energy to create lesions in tissue by coagulation necrosis." Ex. H at 5. 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. 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. Lesions are caused by changing the temperature of the tissue. Ex. K at 1.

Claims of USP 10,610,675	Neuromark system and method using Neuromark system
	Ex. K at 1. • Brian Shields, Neurent’s founder and CEO has confirmed that the Neuromark system creates numerous micro-lesions. 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. • Neurent acknowledges in marketing literature that the delivery of RF energy to the tissue changes the temperature of the tissue, 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 10,610,675	Neuromark system and method using 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.
2. The method of claim 1, wherein administering therapy comprises delivering energy from at least one energy delivery element on the treatment device.	- The Neuromark Device administers therapy from at least one energy delivery element on the device. The end effector on the distal portion of the Neuromark Device has numerous bipolar electrodes for delivering radiofrequency energy, and Neurent instructs physicians to use the device to deliver energy from the electrodes. 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.” Ex. Q at 3.

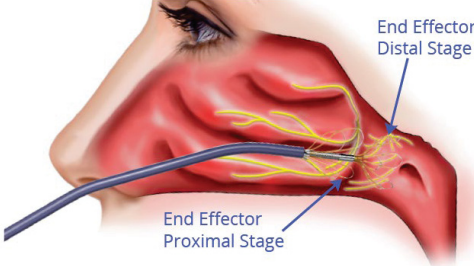
Claims of USP 10,610,675	Neuromark system and method using Neuromark system
	The device is a hand-held, single-use, low-power, bipolar radiofrequency device with an electrode array (end effector) at the device tip (Figure 2). The end effector consists of multiple leaflets, each of which contain several 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.” Ex. H at 5; Ex. I at 4. Electrodes are energy delivering elements. 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.

Claims of USP 10,610,675	Neuromark system and method using Neuromark system
	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.
3. The method of claim 2, wherein the energy comprises RF energy.	- The Neuromark system delivers RF energy through the electrodes on the end effector, and Neurent instructs physicians to use the Neuromark system to deliver RF energy to the target tissue. 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. 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.
7. The method of claim 1, wherein changing the temperature comprises transferring thermal energy between the treatment device and the target tissue.	The RF energy that the Neuromark Device delivers transfers thermal energy from the device to the target tissue to ablate the tissue. Neurent acknowledges in its U.S. Patent No. 11,547,473 that treating rhinitis by using RF energy involves “via one or more electrodes, precise and focused application of RF thermal energy to one or more target sites to thereby therapeutically modulate associated neural structures.” ’473 patent at 2:51-56; <i>see also id.</i> at 3:34-40, 24:49-55, 31:30-42, 32:42-47, 36:28-34.

Claims of USP 10,610,675	Neuromark system and method using Neuromark system
9. The method of claim 1, wherein administering therapy comprises contacting target tissue with a delivery portion of the treatment device.	• The Neuromark Device is intended to be used by having the electrode arrays on the end effector contact the target tissue, and Neurent instructs physicians to contact the target tissue with the end effector. Ex. K at 3. 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> 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. • Neurent instructs physicians to conduct a “baseline bioelectric evaluation to confirm electrode apposition,” i.e., to confirm contact between the end effector and the treatment area. Ex. K at 4; <i>see also</i> Ex. H at 5 (“Using the switch, the user initiates a bio-impedance check, to assess and confirm contact between the end effector and treatment area.”; Ex. I at 4..

Claims of USP 10,610,675	Neuromark system and method using Neuromark system
	Ex. K at 4. 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 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 it to accommodate variations in anatomy to access the desired treatment area. 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. The NEUROMARK® Device is intended for single use and provided sterile (EO). Ex. I at 4. • To make sure that contact with the target tissue is achieved, the Neuromark system allows for “[a]ny leaflets that were not contacting the tissue during first placement” to

Claims of USP 10,610,675	Neuromark system and method using Neuromark system
	be repositioned and made available for treatment. Ex. K at 4. And Neurent instructs physicians to attempt positioning these leaflets to complete a treatment with these leaflets. Ex. K at 4.
10. The method of claim 9, wherein the target tissue is contacted without penetrating the target tissue.	The end effector of the Neuromark Device does not penetrate the target tissue. The end effector is place against nasal tissue. Neurent makes clear the end effector is placed in “mucosal apposition on the lateral wall” of the nasal cavity. Ex. K at 3.

Claims of USP 10,610,675	Neuromark system and method using 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 3: NEUROMARK Device with deployed end effector accommodating the area of the posterior nasal nerves.

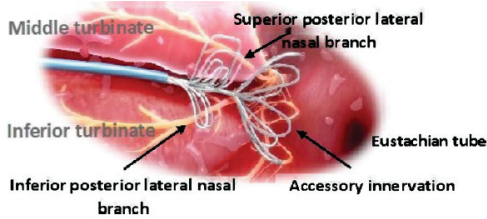
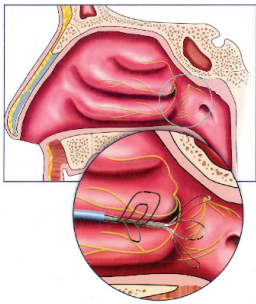
Claims of USP 10,610,675	Neuromark system and method using Neuromark system
	Under endoscopic guidance, the device is introduced into the nasal cavity and advanced to the posterior recesses of the inferior/middle/superior meatus. The distal stage of the end effector is placed in the nasal choanae (posterior 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.
17. A method of treating a nasal condition of a patient comprising:	• The Neuromark system treats chronic rhinitis, which is a nasal condition. Neurent instructs physicians to treat nasal condition of chronic rhinitis with the Neuromark system. • 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 at 3.

Claims of USP 10,610,675	Neuromark system and method using Neuromark system
	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. 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. 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 funded studies to show that the Neuromark system “provides safe and effective treatment to the posterior nasal nerves for patients with chronic rhinitis.” Ex. S at 367. 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 at 367.
positioning a distal portion of a treatment device proximate to target tissue in a	• The Neuromark Device is intended for use in the posterior nasal cavity to target tissue in the nasopharyngeal passage, and Neurent instructs physicians to position the distal portion/end effector of the Neuromark Device proximate to target tissue in the nasopharyngeal passage of a patient.

Claims of USP 10,610,675	Neuromark system and method using Neuromark system
nasopharyngeal passage of a patient; and	- The Neuromark Device has an end effector at the distal end.  Ex. Q at 3. - 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.

Claims of USP 10,610,675	Neuromark system and method using Neuromark system
	From www.bergerhenryent.com/nasal-swell-bodies/. • Neurent repeatedly demonstrates placement of the distal portion of the Neuromark Device proximate to target tissue in a nasopharyngeal passage in its literature, including its Instructions for Use. Figure 3: NEUROMARK Device with deployed end effector accommodating the area of the posterior nasal nerves.

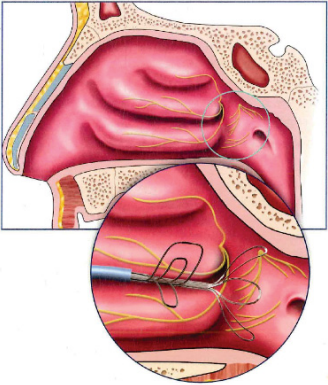
Ex. R at 2.

Claims of USP 10,610,675	Neuromark system and method using Neuromark system
	 FIGURE 2 The NEUOMARK 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. 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 signaling function and the resulting physiological effects of the sub-mucosal glands (rhinorrhea) and venous sinuses (congestion) within the nasal tissue.¹  Go Beyond. Ex. R at 1.

Claims of USP 10,610,675	Neuromark system and method using 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. • Neurent expressly instructs such placement in its Instruction for Use. 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.

Claims of USP 10,610,675	Neuromark system and method using 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.
administering therapy to the target tissue with the treatment device to alter nasopharyngeal cells such that congestion in the nasopharyngeal passage is reduced;	- The Neuromark targets tissue so as disrupt neural activity by altering nasopharyngeal cells to reduce the symptoms of chronic rhinitis, including congestion as shown by Neurent’s 510(k) submission, Instructions for Use, Clarity study, press releases, and other marketing material. Neurent instructs physicians to administer therapy to alter nasopharyngeal cells to reduce congestion in the nasopharyngeal passage. 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. 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 explains that “chronic rhinitis may be caused by abnormal or overactive posterior nasal nerves,” which “can cause mucus creation to go into overdrive creating

Claims of USP 10,610,675	Neuromark system and method using Neuromark system
	a near-constant runny, stuffy nose and/or post-nasal drip.” Use of the Neuromark system is intended provide relief from the “core symptoms,” including relief from congestion. 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. 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

Claims of USP 10,610,675	Neuromark system and method using Neuromark system
	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 • Neurent confirms that the method of therapy provided by the Neuromark system disrupts neural activity. 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.

Claims of USP 10,610,675	Neuromark system and method using Neuromark system
	• Neurent instructs physicians to disrupt neural activity with the Neuromark system and physicians do that to reduce the symptoms of chronic rhinitis, including reducing nasal congestion and postnasal drip significantly. And Neurent funded the Clarity study to demonstrated that using the Neuromark Device and system as instructed by Neurent significantly reduces congestion. 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 10,610,675	Neuromark system and method using 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.
wherein administering therapy comprises delivering energy to the target tissue.	- The Neuromark Device delivers energy to the target tissue. Neurent instructs physicians to use the Neuromark Device to administer therapy by delivering energy to the target tissue. - Neurent’s 510(k) states that the Neuromark applies “radiofrequency energy to create lesions in tissue by coagulation necrosis.” Ex. H at 5. 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. 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.” Ex. K at 1.

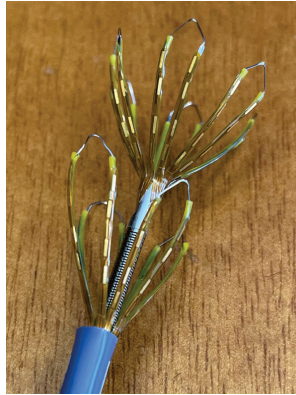
Claims of USP 10,610,675	Neuromark system and method using Neuromark system
	DEVICE DESCRIPTION The NEUROMARK® System is intended for the application of Radiofrequency (RF) energy to create lesions in mucosal tissue in otolaryngological [also known as Ear, Nose and Throat (ENT)] procedures in patients with chronic rhinitis. The NEUROMARK® System is composed of: 1. The NEUROMARK® Device and 2. The NEUROMARK® Radiofrequency (RF) Console Ex. K at 1.
18. The method of claim 17, wherein the energy is delivered from an energy delivery element on the treatment device.	• The Neuromark Device administers therapy from an energy delivery element on the device. The end effector on the distal portion of the Neuromark Device has numerous bipolar electrodes for delivering radiofrequency energy, and Neurent instructs physicians to use the device to deliver energy from the electrodes. 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.”

Claims of USP 10,610,675	Neuromark system and method using Neuromark system
	Figure 2: NEUROMARK Device 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.” Ex. H at 4-5. Electrodes are energy delivering elements. 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.

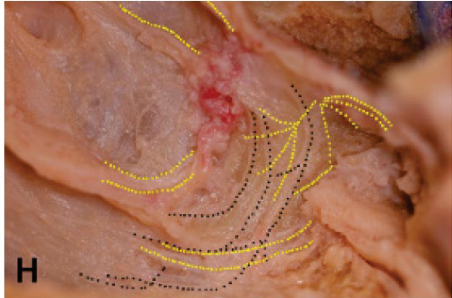
Claims of USP 10,610,675	Neuromark system and method using Neuromark system
	The NEUROMARK® Device is a hand-held, single-use, bipolar radiofrequency device which comprises a handle, shaft, and treatment tip. The treatment tip, which is referred to as the End Effector, consists of an array of bipolar 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.
19. The method of claim 18, wherein the energy comprises RF energy.	- The Neuromark system delivers RF energy through the electrodes on the end effector, and Neurent instructs physicians to use the Neuromark system to deliver RF energy to the target tissue. 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. 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.
20. The method of claim 19, wherein the energy delivery element comprises a monopolar or bipolar electrode.	The Neuromark system delivers RF energy through bipolar electrodes on the end effector.

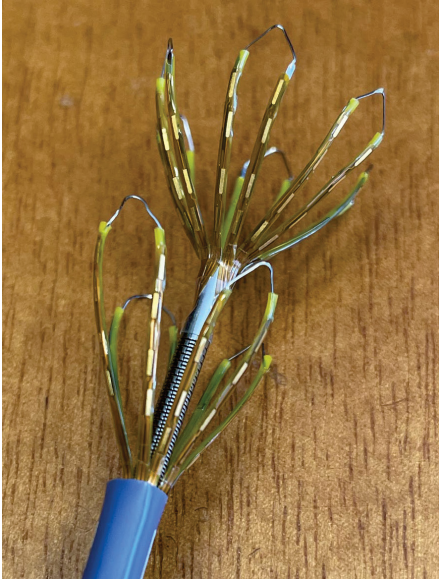
Claims of USP 10,610,675	Neuromark system and method using Neuromark system
	NEUROMARK® Device The NEUROMARK® Device is a hand-held, single-use, bipolar radiofrequency device which comprises a handle, shaft and treatment tip. The treatment tip, which is referred to as the end effector, consists of an 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.  The diagram shows a hand-held device with a handle, a shaft, and a treatment tip. The handle is labeled 'NEUROMARK'. The shaft is curved. The treatment tip is labeled 'End Effector proximal stage' and 'End Effector distal stage'. 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.

Claims of USP 10,610,675	Neuromark system and method using Neuromark system
	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 54.
21. The method of claim 18, wherein the energy delivery element comprises a plurality of electrodes.	• The Neuromark system has a plurality of electrodes in the array of electrodes on the end effector. 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 10,610,675	Neuromark system and method using Neuromark system
	 Figure 2: NEUROMARK Device 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. • A photographic image of the end effector of the Neuromark Device shows a plurality of electrodes. 

Claims of USP 10,610,675	Neuromark system and method using Neuromark system
22. The method of claim 18, wherein the energy delivery element is configured to concentrate energy laterally relative to the distal portion of the treatment device.	- The Neuromark system is designed to concentrate energy laterally relative to the distal portion of the end effector, and Neurent instructs physicians to position the end effector of the Neuromark Device to concentrate energy laterally relative to the distal end of the device. 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. Ex. Q at 2.

Claims of USP 10,610,675	Neuromark system and method using Neuromark system
	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.  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. S at 368.

Claims of USP 10,610,675	Neuromark system and method using Neuromark system
	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.
23. The method of claim 22, wherein the energy delivery element comprises at least one electrode disposed on a lateral side of the distal portion of the treatment device.	• 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 10,610,675	Neuromark system and method using Neuromark system
24. The method of claim 18, further comprising a monitoring electrode or system on the treatment device.	• The Neuromark Device includes multiple monitoring electrodes on the end effector. The electrodes on the end effector deliver RF energy and monitor 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”). • Neuromark’s technical literature 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.
25. The method of claim 24, wherein the monitoring electrode or system comprises a thermocouple, ultrasound transducer, fiberoptic, or sensing or stimulating electrode.	• The Neuromark Device includes multiple monitoring electrodes on the end effector. The electrodes on the end effector deliver RF energy and monitor bioimpedance. • 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 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.