

Exhibit Z

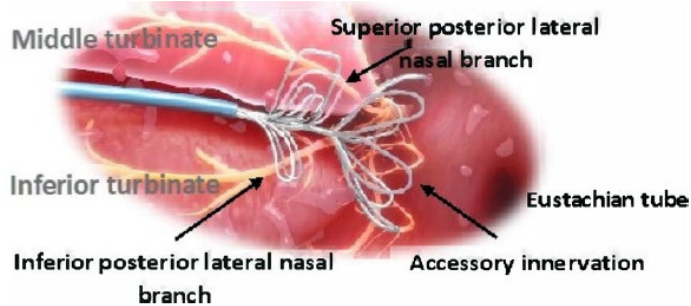
EXHIBIT Z—U.S. Patent No. 11,679,077

Claims of USP 11,679,077	Neuromark system
1. An apparatus for treating rhinitis in a nasal cavity, the apparatus comprising:	• The Neuromark system is an apparatus for treating chronic rhinitis in a nasal cavity. 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.

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	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.
an elongate body, comprising:	The Neuromark system includes the Neuromark Device and Neuromark Generator. Ex. H at 4; Ex. I at 4. The Neuromark Device has an elongate body.  Figure 2: NEUROMARK Device Ex. Q (NEUROMARK® System Mechanism of Action) at 3.
a proximal portion; and	The elongate body of the Neuromark Device has a proximal portion opposite the distal portion.  Figure 2: NEUROMARK Device Ex. Q at 3

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a distal portion configured for positioning in the nasal cavity;	- The elongate body also has a distal portion for positioning in the nasal cavity. The distal portion includes an end effector.  Figure 2: NEUROMARK Device Ex. Q at 3. - The end effector at the distal end “consists of multiple leaflets, each of which contains several bipolar electrode pairs” to create “RF ablation sites” in “nerve rich areas of the lateral wall.” 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. 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.

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	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 the nasal cavity. 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.

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	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.
multiple radiofrequency electrodes coupled with the distal portion of the elongate body; and	The Neuromark Device includes multiple radiofrequency electrodes coupled to the distal end of the elongate body.

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	• The end effector at the distal end of the elongate body of the Neuromark Device has “multiple leaflets, each of which contain several bipolar electrode pairs” and deliver radiofrequency energy. Ex. Q at 2.  The diagram shows a hand-held device with a handle, a long shaft, and a distal end effector. The end effector is shown in two stages: a proximal stage and a distal stage. The distal stage is shown with multiple leaflets, each containing several bipolar electrode pairs. 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 2. • According to Neurent’s Instructions for Use for the Neuromark Device, 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.

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a radiofrequency generator coupled with the proximal portion of the elongate body for supplying radiofrequency energy to the multiple radiofrequency electrodes to treat a target tissue in the nasal cavity and thus treat rhinitis.	• The Neuromark system delivers RF energy through the electrodes on the end effector, and the energy is supplied by an RF generator coupled the proximal portion of the elongate body. Neurent’s 510(k) submissions state that 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. 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.” Ex. L (NEURENT Medical, NEUROMARK Generator, Instructions for Use) at 2. • Neurent stated in its 510(k) that the RF energy is applied “based on the use of a surface contacting electrode array device, connected to an RF generator to apply RF energy to mucosal tissue.” Ex. H at 5.

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	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 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.” (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 even issued a press release touting the Clarity study as demonstrating that the Neuromark device when used as Neurent instructs “demonstrated significant

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	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 multiple radiofrequency electrodes comprise at least two bipolar radiofrequency electrodes.	• The Neuromark Device includes multiple bipolar radiofrequency electrodes. • The Neuromark Device 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 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.

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	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 apparatus of claim 2, further comprising at least one sensing electrode.	• The Neuromark Device includes at least one sensing electrode. 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”). • 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.
4. The apparatus of claim 2, wherein the at least two bipolar radiofrequency electrodes comprise multiple pairs of bipolar radiofrequency electrodes.	• The Neuromark Device includes multiple pairs of bipolar radiofrequency electrodes. • The Neuromark Device includes leaflets “which contain several bipolar electrode pairs,” which constitute multiple pairs of bipolar radiofrequency electrodes. 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.

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5. The apparatus of claim 1, wherein the target tissue comprises nerve tissue.	• The Neuromark system targets nerve tissue. • The indications for use of the Neuromark system indicate that the system targets “nasal nerves.” Ex. H at 3; Ex. I 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. H 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 at 3. • The Neuromark Device seeks to “maximize nerve disruption potential.” 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. • Neurent funded studies to show that the Neuromark system “provides safe and effective treatment to the posterior nasal nerves for patients with chronic rhinitis.”

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	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.
6. The apparatus of claim 1, wherein at least one of the multiple radiofrequency electrodes is movable relative to the distal portion of the elongate body.	• In the Neuromark Device the radiofrequency electrodes are movable relative to the distal portion of the elongate 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.

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	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.
7. The apparatus of claim 1, wherein the multiple radiofrequency electrodes are configured to deliver energy laterally relative to the distal portion of the elongate body.	The Neuromark Device is designed to deliver energy from the end effector laterally relative to the distal portion of the elongate 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.

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	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 “nerve-rich areas on the lateral wall of the nasal cavity” with energy concentrated latterly in the distal end of the device. Ex. Q at 2. 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.

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	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. 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.
8. The apparatus of claim 1, wherein at least one of the multiple radiofrequency electrodes is configured to extend laterally from the distal portion of the elongate body.	• The Neuromark Device has multiple radiofrequency electrodes that extend laterally from the distal portion of the elongate body as the below photograph of the end effector shows.

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11. The apparatus of claim 1, further comprising a monitoring system coupled with the distal portion of the elongate body for monitoring a degree of treatment of the target tissue.	• The Neuromark system includes a monitoring system coupled with the distal portion of the elongate body of the Neuromark Device for monitoring 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

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	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.