September 16, 2022

Phagenesis Limited
℅ Dr. Susan Alpert
Consultant
SFA Regulatory, LLC
2425 L Street NW Apt 307
Washington, DC 20037

Re: DEN220025
Trade/Device Name: Phagenyx System
Regulation Number: 21 CFR 874.5950
Regulation Name: Oropharyngeal electrical stimulator
Regulatory Class: Class II
Product Code: QQG
Dated: April 19, 2022
Received: April 19, 2022

Dear Dr. Alpert:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the Phagenyx System, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> The Phagenyx System is a neurostimulation device delivering electrical stimulation to the oropharynx, to be used in addition to standard dysphagia care, as an aid to improve swallowing in patients with severe dysphagia post stroke.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Phagenyx System, and substantially equivalent devices of this generic type, into Class II under the generic name Oropharyngeal Electrical Stimulator.

FDA identifies this generic type of device as:

> **Oropharyngeal electrical stimulator**. An oropharyngeal electrical stimulator is a device that stimulates afferent nerve fibers of oropharyngeal mucosa. The device is intended to treat swallowing dysfunction. The device may incorporate a feeding tube.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE)

determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On April 19, 2022, FDA received your De Novo requesting classification of the Phagenyx System. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Phagenyx System into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the Phagenyx System can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Identified Risks to Health	**Mitigation Measures**
Incorrect stimulation output leading to discomfort or delayed treatment, or incorrect location of stimuli leading to jaw chattering or facial/ear pain	Non-clinical performance testing Software verification, validation and hazard analysis Usability testing Training
Off target neurostimulation due to patient specific injury resulting in harmful neurological activity	Usability testing Training
Tissue damage due to mechanical stress, electrical effects, or heating effects	Usability testing Training Electrical safety testing
Electrical shock from electrical component malfunction	Non-clinical performance testing Electrical safety testing
Interference with other devices leading to malfunction or injury	Electromagnetic compatibility (EMC) testing
Adverse tissue reaction	Biocompatibility evaluation
Infection	Sterilization validation Reprocessing validation Shelf life testing Labeling
Software failure leading to delayed treatment or discomfort	Software verification, validation and hazard analysis
Fire hazard in the presence of supplementary oxygen	Non-clinical performance testing Training
For devices with feeding tubes, leakage and misplacement of feeding	Non-clinical performance testing Training

tube leading to feeding-related complications (e.g., temporary suboptimal nutrition, reflux aspiration, respiratory distress)	Usability testing

In combination with the general controls of the FD&C Act, the oropharyngeal electrical stimulator is subject to the following special controls:

(1) Non-clinical performance testing must demonstrate the device performs as intended under anticipated conditions of use, including the following:

(i) Electrical output testing;
(ii) Mechanical integrity testing of electrical components;
(iii) Testing to verify safe use of the electrical stimulator component in the presence of supplementary oxygen; and
(iv) If the device incorporates a feeding tube, feeding tube functionality testing, including mechanical integrity, liquid leakage, flow rate and connector compatibility.

(2) The patient-contacting components of the device must be demonstrated to be biocompatible.

(3) Performance testing must demonstrate the sterility of the components intended to be provided sterile.

(4) Performance data must validate the reprocessing instructions for any reusable components of the device.

(5) Performance testing must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the labeled shelf life.

(6) Software verification, validation and hazard analysis must be performed for any software components of the device.

(7) Performance testing must demonstrate the electromagnetic compatibility (EMC) and electrical safety of any electrical components.

(8) A training program must be included with sufficient educational elements so that upon completion of the training program, the users can correctly operate the device.

(9) Usability testing must demonstrate that the device can be correctly used as per training and labeling.

(10) The labeling must include a shelf life for any sterile components.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the oropharyngeal electrical stimulator they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD&C Act; 21 CFR 1000-1050).

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

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

If you have any questions concerning the contents of the letter, please contact Sunny Park at 301-796-7059.

Sincerely,

Denise L. Hampton -S

for Malvina B. Eydelman, M.D.
Director
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health