June 16, 2023

Invictus Medical, Inc.
% Isabella Schmitt
Director of Regulatory Affairs
Proxima Clinical Research
2450 Holcombe Blvd
Houston, Texas 77021

Re: DEN220048
Trade/Device Name: Neoasis
Regulation Number: 21 CFR 880.5405
Regulation Name: Active noise attenuation system for infant incubators
Regulatory Class: Class II
Product Code: QWX
Dated: March 31, 2023
Received: April 8, 2023

Dear Isabella Schmitt:

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 Neoasis, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> The Neoasis® device is intended to reduce noise levels inside an infant incubator in the neonatal intensive care unit (NICU). The attenuation performance of the device is for noises in the NICU with frequencies between 250 Hz to 1,000 Hz.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Neoasis, and substantially equivalent devices of this generic type, into Class II under the generic name active noise attenuation system for infant incubators.

FDA identifies this generic type of device as:

> **Active noise attenuation system for infant incubators**. A device system which captures the environmental noise and outputs noise cancelling acoustic sound waves to attenuate noise in infant incubators in the healthcare environment.

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 July 25, 2022, FDA received your De Novo requesting classification of the Neoasis. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Neoasis 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 Neoasis 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:

Risks to Health	**Mitigation Measures**
Hearing loss from high device output or ineffective device attenuation	Non-clinical performance testing Software validation, verification, and hazard analysis Electrical safety and electromagnetic compatibility testing Labeling
Infection	Labeling
Adverse tissue reaction	Biocompatibility evaluation

In combination with the general controls of the FD&C Act, the Active noise attenuation system for clinical use is subject to the following special controls:

(1) Non-clinical performance testing under anticipated conditions of use must demonstrate that the device performs as intended, including:
   (i) Verification and validation of critical acoustic parameters, including the maximum output of the device;
   (ii) Verification and validation of the attenuation performance of the device, including:
      (A) Testing with compatible incubator model(s) and dimensions;
      (B) Attenuation performance testing simulating different infant locations and orientations within the incubator; and
      (C) Testing with relevant noise sources and room configurations.

(2) Software validation, verification, and hazard analysis must be performed.

(3) Electrical safety and electromagnetic compatibility (EMC) testing must be performed for any electrical components of the device.

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

(5) Labeling for the device must include:
(i) Instructions for infant placement and the expected attenuation performance of the device;
(ii) Warnings regarding the risks of exposure to the potential maximum output of the device;
(iii) Methods and instructions for cleaning and disinfection; and
(iv) Identification of the incubator(s) that the device is intended to be used with.

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 Active noise attenuation system for clinical use 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 Gang Peng at 301-348-1960.

Sincerely,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
OHT3: Office of GastroRenal, ObGyn,
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