



December 20, 2018

TIMPEL Inc.
% Paul Dryden
Consultant
R. Simão Álvares, 356 cj. 41 - Pinheiros
São Paulo - SP, 05417-020, Brazil

Re: DEN170072
Trade/Device Name: ENLIGHT 1810
Regulation Number: 21 CFR 868.1505
Regulation Name: Ventilatory electrical impedance tomograph
Regulatory Class: Class II
Product Code: QEB
Dated: September 27, 2017
Received: September 29, 2017

Dear Paul Dryden:

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 ENLIGHT 1810, a prescription device under 21 CFR Part 801.109 with the following indications for use:

ENLIGHT 1810 is a non-invasive, non-radiation medical device that provides information of local impedance variation within a cross-section of a patient's thorax. This information is presented to the clinician user as an adjunctive tool to other clinical information in order to support the user's assessment of variations in regional air content within a cross section of a patient's lungs.

It is intended for mechanically ventilated adult patients in a hospital setting, whose thorax perimeter is within the range of 78-122 cm.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the ENLIGHT 1810, and substantially equivalent devices of this generic type, into Class II under the generic name ventilatory electrical impedance tomograph.

FDA identifies this generic type of device as:

Ventilatory electrical impedance tomograph. A ventilatory electrical impedance tomograph is a prescription non-invasive, non-radiological ventilatory device that provides an assessment of local impedance variation within a cross-section of a patient's thorax.

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 September 29, 2017, FDA received your De Novo requesting classification of the ENLIGHT 1810. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the ENLIGHT 1810 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 ENLIGHT 1810 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:

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risk	Mitigation Measures
Adverse tissue reaction	Biocompatibility evaluation
Electromagnetic interference with other devices	Electromagnetic compatibility testing
Infection	Reprocessing validation, and Labeling
Inaccurate images due to either device hardware or software failure/malfunction	Software verification, validation, and hazard analysis; Non-clinical performance testing; and Labeling
Electrical shock injury or thermal injury	Electrical, thermal, and mechanical safety testing; Software verification, validation and hazard analysis; Non-clinical performance testing; and Labeling

In combination with the general controls of the FD&C Act, the ventilatory electrical impedance tomograph is subject to the following special controls:

1. The patient-contacting components of the device must be demonstrated to be biocompatible.
2. Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use, including the following:
 - a. Characterization of device parameters, including signal to noise ratio, voltage accuracy, drift, reciprocity accuracy, amplitude response, position error, and ringing;
 - b. Real time evaluation of local impedance variation;

- c. Plethysmogram accuracy testing; and
 - d. Use life testing of reusable components.
3. Performance data must validate reprocessing instructions for any reusable components of the device.
4. Performance data must demonstrate the electrical, thermal, and mechanical safety and the electromagnetic compatibility of the device.
5. Software verification, validation, and hazard analysis must be performed.
6. Labeling must include the following:
 - a. Guidance for interpretation of the images generated;
 - b. A warning that the device should be removed before use of a defibrillator, or defibrillator interaction information based on defibrillator performance testing with the device;
 - c. A use life for any reusable components; and
 - d. Instructions for reprocessing any reusable 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 ventilatory electrical impedance tomograph 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/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 Deepika Arora Lakhani at 301-796-4042.

Sincerely,

Angela C. Krueger
Deputy Director, Engineering and Science Review
Office of Device Evaluation
Center for Devices and Radiological Health