January 6, 2022

Timpel S.A.
% Paul Dryden
Consultant
ProMedic Consulting LLC
131 Bay Point Dr NE
Saint Petersburg, Florida 33704

Re: K211135
Trade/Device Name: Enlight 2100
Regulation Number: 21 CFR 868.1505
Regulation Name: Ventilatory Electrical Impedance Tomograph
Regulatory Class: Class II
Product Code: QEB
Dated: December 6, 2021
Received: December 8, 2021

Dear Paul Dryden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the 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 Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, 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).

Sincerely,

Brandon Blakely, Ph.D.
Assistant Director
DHT1C: Division of Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement on last page.

510(k) Number *(if known)*

K211135

Device Name

Enlight 2100

Indications for Use *(Describe)*

ENLIGHT 2100 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 and pediatric patients in a hospital setting, whose thorax perimeter is within the range of 37.5 - 134cm.

ENLIGHT 2100 does not measure regional ventilation of the lungs.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services Food and Drug Administration
Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff *PRAStaff@fda.hhs.gov*

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Date Prepared:	6-Jan-22
Sponsor:	TIMPEL S.A. Rua Simão Álvares, 356 Cj. 41/42 Pinheiros, São Paulo/SP - Brazil T - +55-113088-0305 E - Rafael.holzhacker@timpelmedical.com
Submission Correspondent:	Paul Dryden ProMedic, LLC 131 Bay Point Dr NE St. Petersburg, FL 33704
Proprietary or Trade Name:	ENLIGHT 2100 US
Regulation Number: **Regulation Name:** **Product code:**	21 CFR 868.1505 Ventilatory electrical impedance tomograph QEB
Predicate Device:	Timpel – ENLIGHT 1810 – DEN170072

Device Description:
ENLIGHT 2100 is a Ventilatory electrical impedance tomograph that uses several electrodes (usually between 16 and 32) placed around the patient's thorax to assess regional impedance variation in a lung slice (tomography). It provides a relative measurement, so it only provides information on variations in local impedance.

ENLIGHT 2100 estimates Local Impedance Variation, occurring in a cross section of the thorax during a respiratory cycles, and which are linearly related to Variations in Regional Air Content within the lung.

Principle of Operation:
Electrical impedance tomography (EIT) is a technique in which the electrical properties of tissues are estimated from surface electrode voltage measurements and used to provide information on Local Impedance Variation (LIV) within a cross section of a patient's thorax. Considerable electrical impedivity variations are imposed on lung tissue by variations in the lung's air content.

There is a linear relationship between the variations in air content and the percentage change in lung tissue impedance. This is a characteristic of lung tissue due to the properties of alveoli walls. This linear relationship is explored in Electrical Impedance Tomography, supporting its use as a tool to support the user's assessment of the variations in regional air content within a cross section of a patient's lungs.
The electrode voltage measurement can be made at high rates as 50 times / second, making it possible to display Local Impedance Variations with a high temporal resolution, almost continuously.

Indications for Use:
ENLIGHT 2100 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 and pediatric patients in a hospital setting, whose thorax perimeter is within the range of 37.5 – 134 cm.

ENLIGHT 2100 does not measure regional ventilation of the lungs.

Patient Population:
Mechanically ventilated adult and pediatric patients whose thorax perimeter is within the range of 37.5 -134 cm.

Environments of use:
Hospital setting.

Substantial Equivalence Discussion

Indications – There are no differences in the indication for use, besides the patient population.

Patient Population – The intended Patient Population for ENLIGHT 2100 are adult and pediatric patients, whose thorax perimeter is within the range of 37.5 – 134 cm. ENLIGHT 2100 is indicated for mechanically ventilated patients, so the patient is usually sedated, and the application of the electrode belt is performed in uncooperative patients, regardless being adult or pediatric patients. There are no differences in the algorithm or software between different sizes of electrode belt, only the reconstruction meshes are different, but with the same performance.

Environment of Use – There is no difference in the environment of use.

Technological Characteristics – The Operating Principle is the same for ENLIGHT 2100 and ENLIGHT 1810. The hardware system was redesigned, reducing the module volume with improved hardware layout. The digital part of the hardware was redesigned and the analog hardware (driven shields and common mode circuits of acquisition channels) have the same well-proven topology and only layout was improved.

The enclosure also includes the pneumotachograph OEM Module (the same part number used in ENLIGHT 1810) and DC-DC power supplies, that were previously presented within other mechanical enclosures – Hub and power supply enclosure, respectively.

Improvements on power dissipation were implemented, reducing static consumption of operational amplifiers by reducing the voltage of power supplies without compromising performance. ENLIGHT 1810 OEM AC-DC power supply was replaced by a lower power version OEM module of same manufacturer, as the power consumption of ENLIGHT 2100 US is lower than its predecessor. There is no battery in ENLIGHT 2100 US.

Non-clinical testing

Biocompatibility – There is no difference in the patient contact between the proposed device and the predicate.

Bench testing - We have performed the following performance tests, with similar results between the 2 devices.

Substantial Equivalence Conclusion
Data presented indicated that there is substantial equivalence between ENLIGHT 2100 and ENLIGHT 1810.

Table 5.1 – Comparison – Subject vs. Predicate

Attributes	Subject ENLIGHT 2100	Predicate ENLIGHT 1810	Explanation of Differences
510(k)		DEN170072	
Product Classification CFR	868.1505 – QEB	868.1505 – QEB	Similar
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 and pediatric patients in a hospital setting, whose thorax perimeter is within the range of 37.5 -134 cm. ENLIGHT 2100 does not measure regional ventilation of the lungs.	ENLIGHT 2100 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.	Inclusion of new sizes of accessories and software modifications to expand the patient range.
Patient Population	Pediatric patients, whose thorax perimeter is within the range of 37.5 -134 cm.	Adult patients, whose thorax perimeter is within the range of 78-122 cm.	Inclusion of pediatric patients.
Patient type	Mechanically ventilated patients	Mechanically ventilated patients	No differences.
Prescriptive	Yes	Yes	No differences.
Principle of Operation	Electrical Impedance Tomography based on voltage measures to estimate local impedance variation within a cross-section of a patient's thorax.	Electrical Impedance Tomography based on voltage measures to estimate local impedance variation within a cross-section of a patient's thorax.	No differences.
Contraindications	Declared on Instructions for use	Declared on Instructions for use	No differences.
Environment of Use	Hospital Setting	Hospital Setting	No differences.
Duration of Use	Up to 30 days, with Addere Change each 48 hours.	Up to 30 days, with Addere Change each 48 hours.	No differences.

Attributes	Subject ENLIGHT 2100	Predicate ENLIGHT 1810	Explanation of Differences
Useful life	ENLIGHT 2100 has 7 years of useful life.	ENLIGHT 1810 has 7 years of useful life.	No differences.
Shelf life	Addere has 2 year of shelf life. Electrode Belt has 1 year of shelf life.	Addere has 1 year of shelf life. Electrode Belt has 1 year of shelf life.	There is no change of shelf life for the Electrode Belts, but new validation test data with real-time aged samples increased Addere shelf life from 1 to 2 years.
Non-sterile	There are no sterile components or accessories.	There are no sterile components or accessories.	No differences.
Cleaning methods	Cleaning and disinfection prescribed only for the device. Accessories are single patient use.	Cleaning and disinfection prescribed only for the device. Accessories are single patient use.	No differences.
Features			
Available sizes	Electrode Belt sizes P0, P1, P2, 4S, 5S, XXS, XS, S, M, L, XL Addere sizes P0, P1, P2, 4S, 5S, XXS, XS, S, M, L, XL Shaper No 2 Reference Cable (Single size)	Electrode Belt sizes XS, S, M, L Addere sizes XS, S, M, L Shaper No 2 Reference Cable (Single size)	New Electrode Belts and Addere sizes included to expand the patient range.
Shape	Monitor-like device, transportable	Monitor-like device, mobile, with incorporated cart	Device size is smaller to facilitate the shipping logistics and device handling inside the hospital.
Patient Contact per ISO 10993-1	Surface contact Intact skin Prolonged duration (Up to 30 days)	Surface contact Intact skin Prolonged duration (Up to 30 days)	No differences.

Attributes	Subject ENLIGHT 2100	Predicate ENLIGHT 1810	Explanation of Differences
Performance Characteristics – Bench Test with Electrode Belt size S			
Signal to Noise Ratio (SNR)	(50dB – 95dB)	(50dB - 85dB)	SNR and Drift are both parameters that reflect the precision of data acquisition. SNR indicates the system noise in data acquisition. Drift indicates a long-term stability in data acquisition. ENLIGHT 2100 has slight better performance considering the Signal to Noise Ratio when compared to ENLIGHT 1810. The drift of both devices is similar, as Allan Variance of both devices converge to less than $100pV^2$, which is a negligible value when considering the background noise measured by SNR. ENLIGHT computes normalized difference voltages from the acquired voltages to generate local impedance variation images and not on the absolute voltages itself. The subtraction of a reference voltage reduces the effect of hardware imperfections related to bias and the normalization by a reference voltage reduces the effect of imperfections related to gain. Voltage Accuracy and Reciprocity Accuracy reflect those imperfections even though attenuated by the imaging algorithm. Voltage Accuracy and Reciprocity Accuracy of ENLIGHT 2100 are similar to ENLIGHT 1810, but as indicated above, the imaging quality is not reflected by those parameters.
Voltage Accuracy	(80% - 100%)	(85% - 100%)	
Drift	Allan Variance converges to zero (below $100pV^2$)	Allan Variance converges to zero (below $100pV^2$)	
Reciprocity Accuracy	(95% - 100%)	(96% - 100%)	

Attributes	Subject ENLIGHT 2100	Predicate ENLIGHT 1810	Explanation of Differences
Amplitude response	(90% - 104%)	(94% - 106%)	ENLIGHT 2100 US Infant and ENLIGHT 1810 have similar performance in all parameters related to imaging quality with no significant differences
Position error	Smaller than 4% of the radius	Smaller than 4% of the radius	
Ringing	Smaller than 0.6	Smaller than 0.6	
Resolution	Smaller than 0.42	Smaller than 0.42	
Percentage error of Plethysmogram	Below 5%	Below 5%	ENLIGHT 2100 and ENLIGHT 1810 have similar performance with error below 5%.