March 7, 2023

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

Re: K222897
Trade/Device Name: Enlight 2100
Regulation Number: 21 CFR 868.1505
Regulation Name: Ventilatory Electrical Impedance Tomograph
Regulatory Class: Class II
Product Code: QEB, BZK
Dated: February 6, 2023
Received: February 6, 2023

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,

Ethan L. Nyberg -S

for James Lee
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)*

K222897

Device Name

Enlight 2100

Indications for Use *(Describe)*

ENLIGHT 2100 is a non-invasive, radiation free medical device that provides information from impedance variation from 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 thorax.

ENLIGHT 2100 also provides respiratory parameters based on spirometric monitoring.

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

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.

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510(k) Summary

Date Prepared:	6-Mar-23
Sponsor:	TIMPEL S.A. Rua Simão Álvares, 356 Cj. 41/42 Pinheiros, São Paulo/SP - Brazil T - +55-113088-0305 Rafael Holzhacker - CEO
Submission Correspondent:	Paul Dryden ProMedic, LLC
Proprietary or Trade Name:	ENLIGHT 2100
Regulation Number:	868.1505
Regulation Name:	Ventilatory electrical impedance tomograph
Product code:	QEB
Secondary Product Code:	BZK
Regulation Number:	868.1850
Regulation Name:	Spirometer, Monitoring (W/Wo Alarm)
Primary Predicate:	Primary Predicate - ENLIGHT 2100 - K211135
Regulation Number:	868.1505
Regulation Name:	Ventilatory electrical impedance tomograph
Product code:	QEB
Secondary Predicate:	Philips NM3 Respiratory Profile Monitor with VentAssist – K103578
Regulation Number:	868.1850
Regulation Name:	Spirometer, Monitoring (W/Wo Alarm)
Product Code:	BZK

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 cycle, and which are linearly related to Variations in Regional Air Content within the lung.

Principle of Operation:
Electrical impedance tomography (EIT) provides information on Local Impedance Variation (LIV) within a cross section of a patient's thorax.

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.

ENLIGHT 2100 also provides respiratory parameters based on spirometric monitoring.

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.

Patient Population – There is no difference in the patient population.

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

Technological Characteristics – There are no technological characteristic differences between either the Enlight 2100 or NM3 and the technology is the same as the NM3 cleared under K103578 which is a pneumotach with flow sensor.

Parameters - The subject device provides numerical calculation from data already present in the secondary predicate device, to complement the Trends Screen. Numerical data will be used as reference for trend analysis, in other words, to compare different moments during the continuous monitoring of the same patient.

There are no standard values or expectations related to the parameters shown, as well as clinical significance for the absolute values. Variations of the same parameter shall be used as 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 thorax.

Non-clinical testing

Biocompatibility – There is no difference in the patient contact or materials between the proposed device and the predicates.

Human Factors – There are no changes in the primary functions of the device or risk control measures that require new human factors validation.

Bench Testing - We have performed performance tests to check the automatic calculation of the parameters shown at the Trend Screen.

The following non-clinical testing was performed to support substantial equivalence. Details of the test results are provided in the tables below.

- EIT Parameters
    - Distribution ratios
    - TVz – Tidal Variation Z
    - TVR – Tidal Variation Rate
- Airway Ventilation Parameters
- Airway Ventilation Parameters
- Alveolar Parameters

- Ventilation Parameters for adult / pediatric flow sensor
    - Compliance
    - Resistance
    - Plateau Pressure
    - Auto PEEP
    - Driving Pressure

For NM3, K103578, as a secondary predicate device

Indications –ENLIGHT 2100 will provide only a subset of the spirometric monitoring for pediatric and adult patients, to complement it as an adjunctive tool to support the user's assessment of variations in regional air content.

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 and neonates above 29 days. The intended patient population for ENLIGHT 2100 is not the same as NM3, but it's included in the range of intended patient population of the predicate device.

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

Technological Characteristics – The technology is the same as the NM3 cleared under K103578 which is a pneumotach with flow sensor.

Standards - We referenced the following FDA recognized standards.

- [Rec. Number 19-4] AAMI ANSI ES 60601-1: 2005 / (R)2012 and A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- [Rec. Number 19-1] IEC 60601-1-2 ed. 4: 2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests

Substantial Equivalence Conclusion

The data presented supports the substantial equivalence between the subject device ENLIGHT 2100, ENLIGHT 2100 cleared under K211135 and NM3 (spirometric measurements subset), cleared under K103578.

Table 1 – Comparison – Subject vs. Primary Predicate – EIT Data

Attributes	Subject ENLIGHT 2100 – K232897	Primary Predicate ENLIGHT 2100 - K211135	Explanation of Differences
Indications for Use	ENLIGHT 2100 is a non-invasive, radiation free medical device that provides information from impedance variation from 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. ENLIGHT 2100 also provides respiratory parameters based on spirometric monitoring. 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.	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.	The change in the Indications for Use is related only to the inclusion of respiratory parameters, which are equivalent to the other predicate claimed.
Patient Population	Adult and Pediatric patients, whose thorax perimeter is within the range of 37.5 -134 cm.	Adult and Pediatric patients, whose thorax perimeter is within the range of 37.5 -134 cm.	No differences.
Patient type	Mechanically ventilated patients	Mechanically ventilated patients	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	No changes, presented in Instructions for use	No changes, presented in 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.
Operating System	Update of the version of Linux OS and Open Source Software for the Processing and Interface Module (PIM).	The PIM software runs on top of a Linux OS, using JAVA.	The differences do not impact the software structure. There are no differences to the end user.

Attributes	Subject ENLIGHT 2100 – K232897	Primary Predicate ENLIGHT 2100 - K211135	Explanation of Differences
Features			
Accessories / Available Sizes	Electrode Belt sizes – 11 sizes Addere sizes – 11 sizes Shaper No 2 Reference Cable (Single size)	Electrode Belt sizes – 11 sizes Addere sizes – 11 sizes Shaper No 2 Reference Cable (Single size)	No differences.
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.
Trends Screen	Data from the device is presented to the user in graphic format and with possibility to compare two moments (reference and cursor) to assist the user in the patient assessment.	Data from the device is presented to the user in graphic format and with possibility to compare two moments (reference and cursor) to assist the user in the patient assessment.	Numerical data are automations of calculations that could be done manually using the predicate device.
Trends Screen Distribution Ratios	Graphic Information for Global and Regional (Anterior / Posterior / Right / Left) Plethysmograms, with numerical indications of tidal variations (Δ) for the period indicated by the reference and cursor lines (defined by the user), color coded.	Graphic Information for Global and Regional (Anterior / Posterior / Right / Left) Plethysmograms, with numerical indications of tidal variations (Δ) for the period indicated by the reference and cursor lines (defined by the user), color coded.	Calculates and displays the Relationship between the amplitude of the regional plethysmograms (Anterior / Posterior / Right / Left) and the amplitude of the global plethysmogram, in percentage.
Trends Screen Tidal Variation Z	The device automates the calculation that could be done by the user. It calculates the maximum impedance variation for the respiratory cycle in which the reference is positioned, and also calculates the maximum impedance variation for the respiratory cycle in which the cursor is positioned. These values are called "**Tidal Impedance Variation**".	In the plethysmogram, the user can see the value of the tidal impedance variation by positioning the reference and cursor lines in the maximum and the minimum value of a certain respiration cycle at a first moment (t1). (Δ1 in blue, in the example above). By selecting the maximum and the minimum values in a different cycle (t2), it is possible to manually calculate the ratio of the Tidal Impedance Variation between those 2 moments (Δ1 assessed in t2 divided by Δ1 assessed in t1).	It calculates and displays the a) maximum impedance variation for the respiratory cycle in which the reference is positioned, b) the maximum impedance variation for the respiratory cycle in which the cursor is positioned, and c) the relationship between the maximum impedance variation of these two timepoints.
Trends Screen Tidal Variation Rate	The device calculates the **Tidal Variation Rate**, considering number of oscillations that were identified in the last minute. This data is presented in the Numerical Area (table) and in graphical form in the trends screen.	In the global plethysmogram, the user can count how many oscillations of the plethysmogram he observes within the time period between the reference and cursor lines, and calculate how many oscillations per minute occurred.	The device calculates and displays the Tidal Variation Rate, considering the last minute.

Attributes	Subject ENLIGHT 2100 – K232897	Primary Predicate ENLIGHT 2100 - K211135	Explanation of Differences
Performance Characteristics – Non-clinical / Bench Test			
Distribution Ratios	Range: 0 – 100% Uncertainty of +/- 10 p.p. for Anterior, Posterior, Left and Right distribution ratio.	Same	The predicate didn't present the numeric parameter, but as the hardware is the same and the EIT algorithm is the same, the performance is equivalent for this characteristic.
Tidal Variation Z (TVz)	Range: 20% to 500% Uncertainty of +/- 10% of reading.	Same	
Tidal Variation Rate	Adult: 5 to 50 bpm, Pediatric: 10 to 140 bpm ±2.0 bpm if ≤ 60 bpm, ±5.0 bpm if > 60 bpm	Same	

Table 2: Comparison of Subject vs. Secondary Predicate – Ventilatory Data

Attributes	Subject ENLIGHT 2100	Secondary Predicate NM3	Explanation of Differences
510(k)	K222897	K103578	
Product Classification CFR	868.1850 – BZK	868.1850 – BZK	Different product codes. Adding product code of the reference.
Indications for Use	ENLIGHT 2100 is a non-invasive, radiation free medical device that provides information from impedance variation from 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. ENLIGHT 2100 also provides respiratory parameters based on spirometric monitoring. 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.	The intended use of the Philips NM3 Respiratory Profile Monitor, Model 7900, is to provide: Cardiac output monitoring via the method of partial rebreathing in adult patients receiving mechanical ventilation during general anesthesia and in the intensive care unit (ICU); **Spirometric**, and carbon dioxide monitoring in neonatal, **pediatric and adult patients during general anesthesia and in the intensive care unit (ICU)** and the emergency department (ED). Separate combination CO_2/flow sensors are provided for adult, pediatric and neonatal use. Continuous, non-invasive monitoring of functional arterial oxygen saturation and pulse rate in neonatal, pediatric and adult patients during both no motion and motion conditions and for patients who are well or poorly perfused during general anesthesia and in the intensive care unit (ICU) and the emergency department (ED).	ENLIGHT 2100 provides some parameters provided by NM3, so most of the Indications for Use are different. ENLIGHT 2100 will provide only a subset of the spirometric monitoring for pediatric and adult patients, to complement it as an adjunctive tool to support the user's assessment of variations in regional air content.
Patient Population	Adult and Pediatric patients, whose thorax perimeter is within the range of 37.5 -134 cm.	Adult, pediatric and neonatal patients	Does not include neonatal patients.
Patient type	Mechanically ventilated patients	Mechanically ventilated patients	No differences.

Attributes	Subject ENLIGHT 2100	Secondary Predicate NM3	Explanation of Differences
Principle of Operation	ENLIGHT 2100 already includes the FloTrak pneumotachograph internally and the flow sensor as an accessory. ENLIGHT 2100 uses a fixed orifice flow sensor, in which the pressure drop is proportional to the square of the flow. The flow sensor is available for pediatric / adult range. The flow sensor was cleared in the K963380.	The NM3 monitor comprises the cleared Mercury module and the Capnostat 5 sensor. The NM3 monitor uses fixed orifice flow sensors for spirometric monitoring, in which the pressure drop is proportional to the square of the flow.	Both devices use sensors with the same principle of operation for flow measurement.
Contraindications	Declared on Instructions for use	Declared on Instructions for use	Similar as applicable
Environment of Use	Hospital Setting	Hospital Setting	No differences.
Duration of Use	Up to 30 days, with Addere Change each 48 hours.	Not declared.	ENLIGHT 2100 will not change its duration of use.
Features			
Patient Contact per ISO 10993-1	Externally Communicating Tissue Prolonged duration (Up to 30 days)	Externally Communicating Tissue Prolonged duration (Up to 30 days)	No differences.
Parameters on trend screen	The Trend screen displays a table of numeric parameters and two user-selectable trend graphs. In the graphic, data is updated once every minute. Users can adjust the time frame to shorter or longer periods by pressing the Zoom buttons directly on the graphs. In the table, numeric parameters are presented for the lines positioned in the graphic (reference - REF and cursor - CUR) by the user, with a time stamp.	The TREND screen displays two user-selectable numeric parameters and three user-selectable trend graphs. The time periods are: 1 minute average for the 1 hour trend, 2 minute average for the 2 hour trend, 4 minutes for the 4 hour trend, 8 minutes for the 8 hour trend, 12 minutes for the 12 hour trend and 24 minutes for the 24 hour trend.	Similar

Attributes	Subject ENLIGHT 2100	Secondary Predicate NM3	Explanation of Differences
Performance Characteristics – Non-clinical / Bench Test			
Tidal Volume	Range: 40 to 2500 ml Accuracy: Max Error is less or equal to 11.71mL, Max Relative Error is less of equal to 4.97%	The absolute accuracy of ENLIGHT 2100 related to NM3 is less than 6.27mL and the relative accuracy of ENLIGHT related to NM3 is less than 4.33%	Considering the accuracy results of the comparison for Tidal Volume, Respiratory Rate, PEEP , PIP, Plateau Pressure, Resistance and Compliance, subject and predicate are substantially equivalent. ENLIGHT 2100 provides ventilation data to support the user's interpretation of EIT trends data. The clinical user may refer to the ventilator and patient monitoring device as that trend data is more accurate.
Respiratory Rate	Range: 5 to 150 breath/min Accuracy: Max Error is less or equal to 0.70 bpm	The absolute accuracy of ENLIGHT 2100 related to NM3 is less than 0.39 bpm.	
Positive End Expiratory Pressure (PEEP)	Range: 1.0 – 50.0 cmH_2O Accuracy: Max Error is less or equal to 1.0cmH_2O, Max Relative Error is less of equal to 2.47%.	The absolute accuracy of ENLIGHT 2100 related to NM3 is less than 0.73 cmH_2O.	
Peak Inspiratory Pressure	Range: 1.0 – 120.0 cmH_2O Accuracy: Max Error is less or equal to 0.44 cmH_2O	The relative accuracy of ENLIGHT 2100 related to NM3 is less than 4.88%.	
Resistance	Range: 5 – 40 cmH2O/L/s Accuracy: Bias:0 cmH2O/L/s, Std Dev: 3 cmH2O/L/s	The absolute mean accuracy of ENLIGHT 2100 related to NM3 is less than 6 cmH_2O/L/s.	
Compliance	Range: 3 – 80 ml/cmH2O Accuracy: Bias: -1 mL/cmH2O, Std. Dev: 5 mL/cmH2O	The absolute mean accuracy of ENLIGHT 2100 related to NM3 is less than 6.97 mL/cmH_2O.	
Plateau Pressure	Range: 10.0 – 90.0 cmH2O Accuracy: Bias: 0.1 cmH2O, Std Dev:1.1 cmH2O	The absolute mean accuracy of ENLIGHT 2100 related to NM3 is less than 1.47 cmH_2O.	