September 10, 2025

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

Re: K250464
Trade/Device Name: Enlight 2100 (TPL-E2103-0)
Regulation Number: 21 CFR 868.1505
Regulation Name: Ventilatory Electrical Impedance Tomograph
Regulatory Class: Class II
Product Code: QEB, BZK
Dated: February 16, 2025
Received: February 18, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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

Ethan Nyberg, Ph.D.
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep Devices
OHT1: Office of Ophthalmic, Anesthesia,
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250464

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 patients, from adults to infants, older than 29 days, 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
8-Sep-25

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 Consulting, LLC
Proprietary or Trade Name:	ENLIGHT 2100
Regulation Number:	868.1505
Regulation Name:	Ventilatory electrical impedance tomograph
Product code:	QEB
Predicate:	ENLIGHT 2100 - K222897
Regulation Number:	868.1505
Regulation Name:	Ventilatory electrical impedance tomograph
Product code:	QEB

Device Description:
ENLIGHT 2100 is a Ventilatory electrical impedance tomograph that uses several electrodes (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, 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 patients, from adults to infants, older than 29 days, 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 differences in the Technological Characteristics. There is no hardware change, and the algorithms related to EIT data are not modified.

Software Change – The Processing and Interface Module (PIM) is responsible for the interface to the user. The differences do not impact on the software structure. Software verification and validation were executed to ensure the device's safety and performance.

Parameters - The subject device will include parameters related to the already cleared Distribution Change Map, normalized by Driving Pressure, to complement the information of local impedance variation.

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.

Cleaning methods – Electrode belt and reference cable are now reusable. These reusable parts are not intended to contact the patient. There is no change in material or hardware. Cleaning instructions are described in the instructions for use.

Non-clinical testing

Biocompatibility – There is no difference in the patient contact or materials between the proposed device and the predicate. Prior testing has been leveraged to support biocompatibility.

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 obtained at the Trend Screen.

- EIT Parameters
  - ΔEEZ
  - Percentage of Higher Pressure Compliance$_z$ Loss (HPCzL)
  - Percentage of Lower Pressure Compliance$_z$ Loss (LPCzL)

Substantial Equivalence Conclusion

The ENLIGHT 2100 has the same indications for use as the predicate device, and there are no differences in technological characteristics which would raise different questions of safety and effectiveness. Therefore, these devices are substantially equivalent.

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

Attributes	Subject ENLIGHT 2100	Predicate ENLIGHT 2100	Explanation of Differences
510(k)	TBD	K222897	New 510(k) number
Product Classification 21 CFR	868.1505 – QEB	868.1505 – QEB	Same product code.
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 thorax. ENLIGHT 2100 also provides respiratory parameters based on spirometric monitoring. It is intended for mechanically ventilated patients, from adults to infants, older than 29 days, 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, 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.	Similar
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.	Similar
Patient type	Mechanically ventilated patients	Mechanically ventilated patients	Similar
Prescriptive	Yes	Yes	Similar

Attributes	Subject ENLIGHT 2100	Predicate ENLIGHT 2100	Explanation of 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.	Similar
Contraindications	No changes, presented in Instructions for use	No changes, presented in Instructions for use	Similar
Environment of Use	Hospital Setting	Hospital Setting	Similar
Duration of Use	Up to 30 days, with Addere Change each 48 hours.	Up to 30 days, with Addere Change each 48 hours.	Similar
Service-life	ENLIGHT 2100 has 7 years of useful life. Electrode Belt and Reference Cable have 2 years of useful life.	ENLIGHT 2100 has 7 years of useful life. Electrode Belt and Reference Cable have 2 years of useful life.	Similar
Shelf life	Addere has 2 year of shelf life. Electrode Belt has 1 year of shelf life.	Addere has 2 year of shelf life. Electrode Belt has 1 year of shelf life.	Similar
Non-sterile	There are no sterile components or accessories.	There are no sterile components or accessories.	Similar
Cleaning methods	Cleaning and disinfection for the main device, electrode belt and reference cable. Shaper and Addere (which are the accessories that get in contact with the patient) remain as single patient use.	Cleaning and disinfection only for the main device. Accessories are single patient use (electrode belt, reference cable, Addere and Shaper).	Electrode belt and reference cable are now reusable.
Operating System	Yocto based Linux OS for the Processing and Interface Module (PIM).	Yocto based Linux OS for the Processing and Interface Module (PIM)	Similar
Features			

Attributes	Subject ENLIGHT 2100	Predicate ENLIGHT 2100	Explanation of Differences
Accessories / 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 1 and Shaper No 2 Reference Cable (Single size)	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)	Adding a Shaper size does not raise any new risks compared to the predicate.
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)	Similar
Image Screen	Change of the screen name to Distribution Screen:	Screen Name - Images Screen:	Change of the screen name from Image Screen to Distribution Screen. Distribution Screen displays the same “Dynamic Image” and “Distribution Map” as the Images Screen.
Distribution Screen	Distribution Screen displays Distribution Map (updated at every breath), Dynamic Image (updated continuously), and A/P and R/L ratios, updated every 30 seconds.	Images Screen displays Distribution Map (updated at every breath) and Dynamic Image (updated continuously). The Trend Screen displays A/P and R/L ratios, updated every 30 seconds.	The subject device will display on the Distribution Screen the A/P and R/L ratios that users can already see on the predicate device’s Trends Screen
Distribution Screen	Distribution Screen displays Distribution map (updated at every breath), Dynamic Image (updated continuous), as well as respiratory parameters based on spirometric measurements (updated every 30 seconds).	Images Screen displays Distribution map (updated at every breath) and Dynamic Image (updated continuous). The Trend Screen displays respiratory parameters, updated every 30 seconds.	The subject device will display on the Distribution Screen the same respiratory parameters that users can already see in the predicate device’s Trends Screen.

Attributes	Subject ENLIGHT 2100	Predicate ENLIGHT 2100	Explanation of Differences
Trends Screen (Layout 1 - Two Graphs and Distribution Change Map)	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's assessment: Data in the trend is kept for 48 hours of continuous monitoring. The user can select two time points for comparison: reference and cursor. Time stamp of the selected moments (reference and cursor) by the user are shown	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's assessment: Data in the trend is kept for 48 hours of continuous monitoring. The user can select two time points for comparison: reference and cursor. Time stamp of the selected moments (reference and cursor) by the user are shown.	Similar
Trends Screen (Layout 2 – Multi-Step)	The Compliance$_z$ Change Map at the MultiStep Layout represents the comparison of more than two Compliance$_z$ Maps, selected by the user. At the Compliance$_z$ Change Map, regions classified as Lower Pressure Compliance$_z$ Loss (LPC$_z$L) are shown in blue, while regions classified as Higher Pressure Compliance$_z$ Loss (HPC$_z$L) are shown in white. The percentages of LPC$_z$L and HPC$_z$L observed in a Compliance$_z$ Change Map are displayed.	Distribution Change Map represents the comparison between two Distribution Maps selected by the user, normalized by driving pressure. At the Distribution Change Map, regions with increased impedance variation normalized by driving pressure (increased Compliance$_z$) are shown in gold, while regions with decreased impedance variation normalized by driving pressure (decreased Compliance$_z$) are shown in silver.	The predicate device enables users to compare two Maps, while the MultiStep Layout of the subject device allows users to compare multiple Maps at the same time. The results of the comparison among more than two maps at the subject device are shown in blue and white (instead of gold and silver as the predicate device). The percentages of regions identified as LPC$_z$L and HPC$_z$L are also displayed.
Trends Screen End Expiratory Impedance (EEZ)	The subject device automatically identifies the baseline of the plethysmogram and displays the EEZ in a graph. In addition to the graph, the device displays ΔEEZ between REF and CUR as the change in EEZ divided by the TVz at the REF.	The user can obtain the baseline of the plethysmogram (equivalent to EEZ) by placing the cursors (reference and cursor) on the baseline of the plethysmogram. The user can calculate the ΔEEZ by positioning the reference and cursor on the baselines of the plethysmogram, and dividing the difference by the TVz value read at REF on the TVz graph.	The subject device will automate a calculation that could be done manually using the predicate device.

Attributes	Subject ENLIGHT 2100	Predicate ENLIGHT 2100	Explanation of Differences
Compliance$_z$ Change Display	The Compliance$_z$ Change Map at the Compliance$_z$ Change Display represents the comparison of more than two Compliance$_z$ Maps, acquired by the device according to configurations defined by the user. At the Compliance$_z$ Change Map, regions classified as Lower Pressure Compliance$_z$ Loss (LPC$_z$L) are shown in blue, while regions classified as Higher Pressure Compliance$_z$ Loss (HPC$_z$L) are shown in white. The percentages of LPC$_z$L and HPC$_z$L observed in a Compliance$_z$ Change Map are displayed and plotted in a graph.	Distribution Change Map represents the comparison between two Distribution Maps selected by the user, normalized by driving pressure. At the Distribution Change Map, regions with increased impedance variation normalized by driving pressure (increased Compliance$_z$) are shown in gold, while regions with decreased impedance variation normalized by driving pressure (decreased Compliance$_z$) are shown in silver.	The predicate device enables users to compare two Maps, while the Compliance$_z$ Change Display of the subject device allows users to compare multiple Maps at the same time. The results of the comparison among more than two maps at the subject device are shown in blue and white (instead of gold and silver as the predicate device). The percentages of regions identified as LPC$_z$L and HPC$_z$L are also displayed. The results of the comparison among more than two maps at the subject device are shown in blue and white (instead of gold and silver as the predicate device). The percentages of regions identified as LPC$_z$L and HPC$_z$L are also displayed and plotted.
Performance Characteristics – Bench Test			
ΔEEZ	For the range between -15.0 and +15.0, uncertainty of +/- (0.1 + 10% of reading)	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.

Attributes	Subject ENLIGHT 2100	Predicate ENLIGHT 2100	Explanation of Differences
Percentage of Higher Pressure Compliance$_z$ Loss (HPC$_z$L)	Difference between reference and actual values of HPCzL (%) and of LPCzL (%) is not larger than 10 (%)	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.
Percentage of Lower Pressure Compliance$_z$ Loss (LPC$_z$L)	Difference between reference and actual values of HPCzL (%) and of LPCzL (%) is not larger than 10 (%)	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.