

**DE NOVO CLASSIFICATION REQUEST FOR
ENLIGHT 1810**

REGULATORY INFORMATION

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.

NEW REGULATION NUMBER: 21 CFR 868.1505

CLASSIFICATION: Class II

PRODUCT CODE: QEB

BACKGROUND

DEVICE NAME: ENLIGHT 1810

SUBMISSION NUMBER: DEN170072

DATE OF DE NOVO: September 29, 2017

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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.

LIMITATIONS

The sale, distribution, and use of the ENLIGHT 1810 are restricted to prescription use in accordance with 21 CFR 801.109.

WARNINGS AND PRECAUTIONS

- Remove the Shaper and open the Electrode Belt prior to patient defibrillation. Protection circuitry of the device may draw part of the energy delivered by the defibrillator if all electrodes are attached to the patient.
- To avoid an electric shock do not touch the Electrode Belt during the defibrillation discharge.
- ENLIGHT 1810 should not be used on pregnant or lactating women since the safety and efficiency for such cases have not been verified.
- ENLIGHT 1810 should not be used on patients with active implantable devices, such as pacemakers, cardioverter defibrillators, or neurostimulators. There is no scientific evidence of safety for the use of this device on patients with active implantable devices.
- ENLIGHT 1810 should not be used in environments with elevated levels of ambient oxygen (such as hyperbaric chambers) oxygen-enriched environments or in the presence of flammable anesthetic gases or any flammable agent. The device may, however, be used in patients receiving oxygen-enriched ventilation.
- ENLIGHT 1810 is MR unsafe.
- ENLIGHT 1810 should not be used in areas of explosion hazard.
- Do not apply the Electrode Belts or Reference Electrode on injured areas of the skin (e.g., burns, open wounds, rashes, etc.).
- Do not reuse the Electrode Belts. They are disposable and single patient use. Re-using Electrode Belts on a new patient may result in cross-infection.

PLEASE REFER TO THE LABELING FOR A MORE COMPLETE LIST OF WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS.

DEVICE DESCRIPTION

ENLIGHT 1810 is a non-invasive, radiation free medical device intended to provide information on the regional distribution of ventilation in a cross-sectional slice of the thorax.

As the total variation in impedance for the thorax corresponds to the total tidal volume, ENLIGHT 1810 can estimate the percentage of tidal volume in regions of interest (ROI) breath by breath, measuring the contribution of the impedance variation of that ROI to the total impedance of the lung.

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 impedance 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 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 device may be used on adult patients undergoing either fully controlled or assisted mechanical ventilation in the ICU environment.

The system components are shown below:

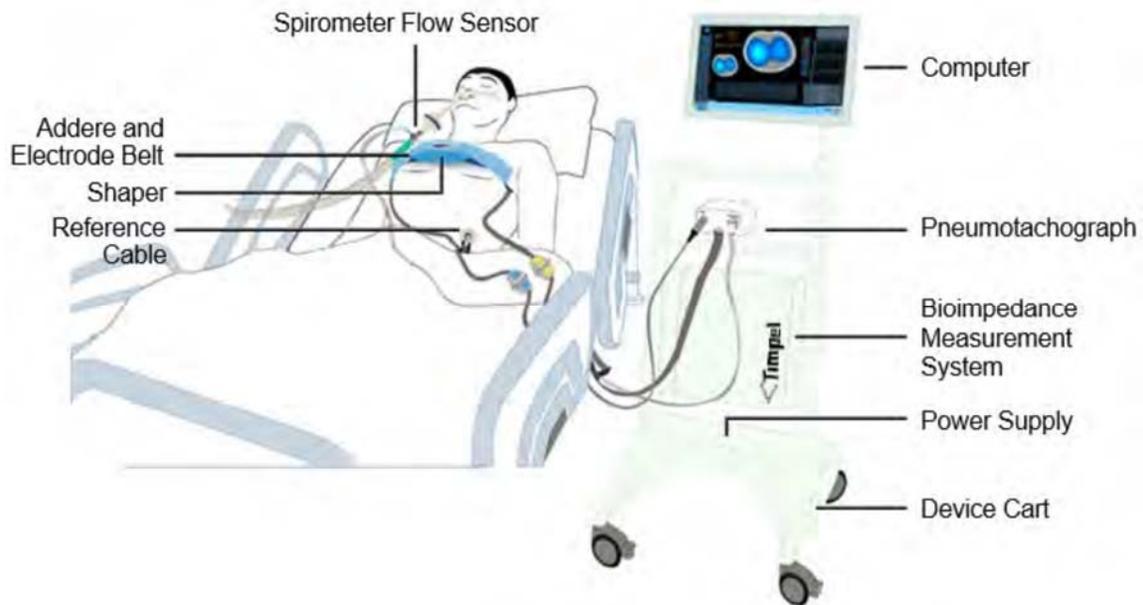


Figure 1. ENLIGHT 1810 System Components

SUMMARY OF NONCLINICAL/BENCH STUDIES

BIOCOMPATIBILITY/MATERIALS

ENLIGHT 1810 includes components (flow sensor) that have externally communicating patient contact via gas pathway for permanent duration. The electrode belt, and shaper have surface contact, intact skin.

The complete device in its final, finished form was subjected to biocompatibility testing in accordance with the FDA guidance document, "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.'" The following tests were conducted to assess biocompatibility of the device for the externally communicating components for permanent duration:

- Cytotoxicity
- Sensitization
- Irritation
- Intracutaneous reactivity
- Extractables and leachables testing with a risk assessment

All tests passed. The results demonstrated the biocompatibility of the device.

SHELF LIFE/REPROCESSING/STERILITY

The following components are single patient use only: the electrode belt, shaper, flow sensor, and reference cable. The Addere and reference electrode are single use only and

must be disposed each time after use.

The surface of the ENLIGHT 1810 hardware undergoes low level cleaning, usually with disinfecting wipes similar to equipment in the ICU. No components are provided sterile.

The cleaning procedures for the single patient use were validated following the recommendations of the FDA Guidance Document “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling”. Data supported that 50 reprocessing cycles did not impact device functionality.

ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY

The ENLIGHT 1810 was tested in accordance with the following consensus standards and conformed with the following electromagnetic compatibility (EMC), electrical, mechanical and thermal safety standards:

- AAMI ANSI ES60601-1:2005/(R)2012 And A1:2012 C1:2009/(R)2012 And A2:2010/(R)2012 (Consolidated Text) Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2005, MOD)
- ANSI AAMI IEC 60601-1-2:2007/(R)2012 Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests (Edition 3)
- The device was also tested for safe exposure to known sources of EMI with medical devices such as MRI, diathermy, and RFID.

MAGNETIC RESONANCE (MR) COMPATIBILITY

The device has not been tested for MRI compatibility and should not be used in an MRI suite.

SOFTWARE

The De Novo request provided adequate software documentation consistent with a “Moderate” level of software concern as discussed in the FDA Guidance Document “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices,” issued May 11, 2005.

Software validation and verification testing demonstrated that the device met its design, implementation, and cybersecurity specifications.

PERFORMANCE TESTING – BENCH

The non-clinical testing for the device consisted of verification and validation testing of hardware and software.

The following bench tests were performed:

- Verification of the following specifications of the EIT system was performed based on experimental saline phantom (proposed by Yasin M et al. (2011).

Evaluation of EIT system performance. Physiological measurement, 32(7), 851). The following performance characteristics were studied using an acrylic cylindrical tank filled with saline and the performance computed using experiments with contrast objects placed in this tank:

- Signal to Noise Ratio: 45 dB-80 dB,
 - Voltage Accuracy: 99.45%-100%,
 - Drift: Allan variance converges to zero,
 - Reciprocity accuracy: 93%-100%,
 - Amplitude response: 88%-102%,
 - Position error: <5% of radius,
 - Ringing: 2-5 σ^2 .
- Uniform phantom testing to estimate the plethysmogram results for an acrylic cylindrical tank filled with saline: The conductivity of the saline solution is set and measured for different values between 0.09 S/m and 0.892 S/m. The difference image of each case is reconstructed using the same reference voltages and the plethysmogram is computed. Fitting (in a least-squares sense) the set of plethysmogram results as a line, the percentage regression residuals are computed. The testing showed that the percentage error of plethysmogram is below 5%.
 - Display of real time information of local impedance variation by application of high frequency current or display an error message if this is not possible.
 - Acquisition Test to verify main functions of the Acquisition Module system: Testing for communication with PIM, command handling, acquisition handling, calibration handling, signal acquisition, hardware handling, file system including configuration recovery and version information of key installed components was completed.
 - Reconstruction Library to verify that the Image Reconstruction Library output matches the results determined analytically: The error between reconstructed output meshes and analytically calculated meshes using the same parameters was measured and verified that the error is below a given threshold.
 - Defibrillation to demonstrate the EIT is safe after undergoing defibrillation shocks if belts/electrodes are not disconnected during RCP/defibrillation maneuvers: Simulations were conducted to estimate energy drawn by EIT equipment. Tests with defibrillator verified energy drawn and if the equipment keeps safety after undergoing defibrillation. The simulation indicated the need to disconnect the patient from ENLIGHT 1810 for defibrillation to avoid loss of treatment efficacy.
 - Use Life Testing was conducted to verify the 50 reprocessing cycles for the single patient use components.

PERFORMANCE TESTING – ANIMAL

Animal studies were conducted to assess the ability of EIT to quantify the ventilation distribution to anterior/posterior and right/left regions of the lungs as compared to X-ray computed tomography (CT) and compare regional ventilation in 4 regions of interest (Anterior / Posterior and Right / Left). Seven swine animals were used. The lung injury was consistent with severe acute respiratory distress syndrome (PaO₂/FiO₂ 89.9 ± 37.7 mmHg). Agreement between EIT and CT for the

anterior/posterior (bias = -0.02 and limits of agreement = -0.09 to 0.06) as well as for the right/left ROIs (bias = 0.04 and limits of agreement = -0.03 to 0.05%) were observed. The proof-of-concept testing provided supportive data on the qualitative clinical performance of the ENLIGHT 1810 device.

PERFORMANCE TESTING – HUMAN FACTORS

The Human Factors Validation (HFV) test was performed to validate all safety-critical and associated essential tasks that are required to use the ENLIGHT® 1810. The first objective of this HFV test was to provide objective performance and subjective interview data to validate those representative users can use the ENLIGHT® 1810 safely when used under representative conditions. A second objective was to verify the adequacy of the Instructions for Use (IFU) and Reference Guide to support user performance and to assess the comprehension of warnings provided in these documents to mitigate risks associated with hazards identified in the ENLIGHT®

The intended users of ENLIGHT® 1810 are healthcare professionals responsible for a patient's ventilation, analyzing the monitored physiological parameters and determining the appropriate ventilatory management. There were 15 users per group. The supplementary Human factors/Usability engineering (HF/UE) reports contained the descriptions of Human factors processes and appropriate validating testing results, data collection, root-cause analyses and conclusion to establish that the ENLIGHT®1810 device and the associated labeling and training are adequate for the intended users, its intended uses, and use environments.

SUMMARY OF CLINICAL INFORMATION

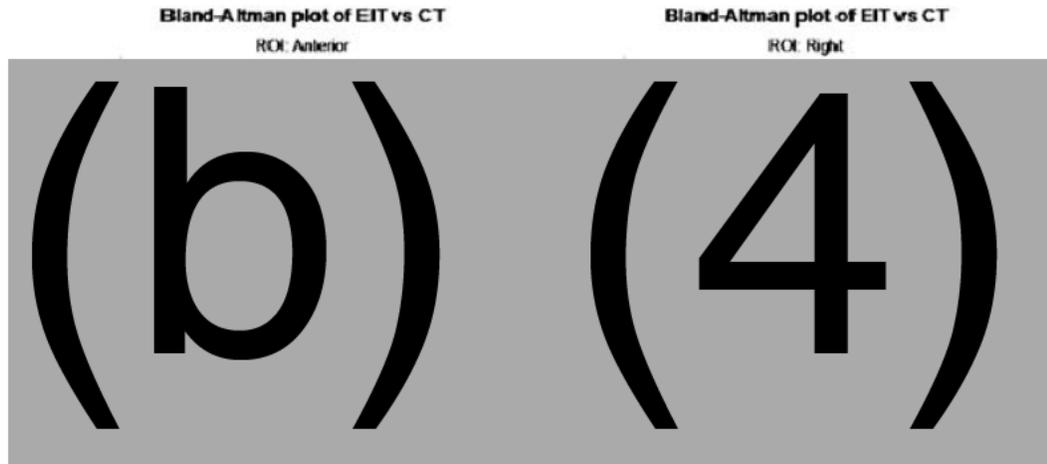
Three clinical studies were conducted to assess the ability of EIT to quantify the ventilation distribution to anterior/posterior and right/left regions of the lungs as compared to X-ray computed tomography (CT) and compare regional ventilation in 4 regions of interest (Anterior / Posterior and Right / Left).

1. Comparison between regional distribution of ventilation: EIT vs. CT

Method: This study evaluated 32/39 healthy volunteers where the ventilation distribution was compared to CT. EIT and CT images were acquired simultaneously in supine, prone and laterals decubitus during 20 seconds of end-expiration and end-inspiration pause. Four thoracic regions of interest (ROI) were defined: anterior, posterior, right, and left. On EIT images, the ROIs represent the division of the thorax in two equal halves both in the anterior/posterior and in the right/left direction. The CT's ROIs were defined based on the midpoint of the lungs in the vertical and horizontal directions.

Endpoints: Evaluated the Ventilation distribution to anterior / posterior and right / left regions of the thorax and assessed the agreement of these distributions to those measured with CT using the same thoracic regions of interest (ROI).

Results: Seven subjects were excluded from the analysis. The statistical evaluations were descriptive, where a Bland-Altman type difference plot was used to compare EIT vs CT with 95% limits of agreement for EIT ventilation distribution to regions of interest in both anterior/posterior and right/left. The study showed that in 32 healthy volunteers the anterior/posterior bias was -0.1 and the limits of agreement was -0.11-0.1 and for the right/left ROI the bias was -0.02 and the limits of agreement was -0.09 to 0.06.



Bland-Altman plots of the ventilation distribution estimated by EIT and CT to the anterior (A) and right (B) regions of interest.

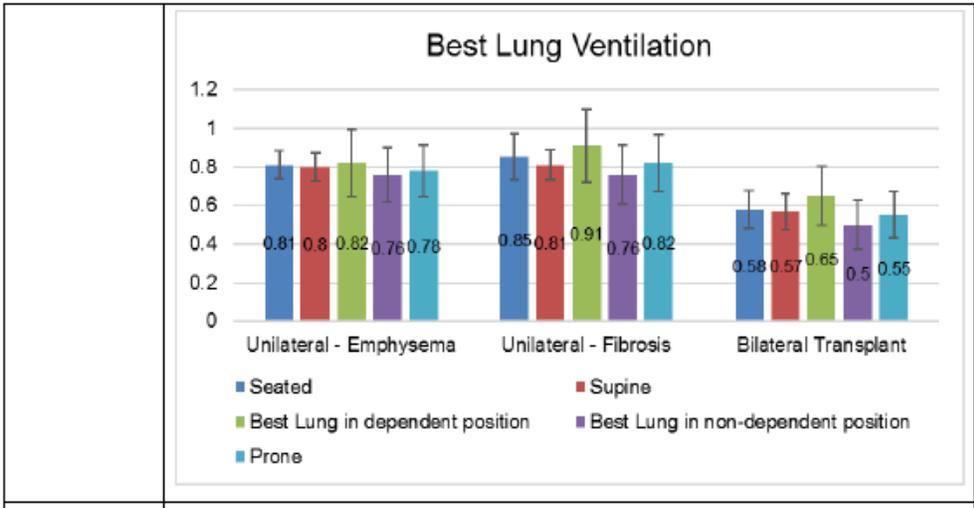
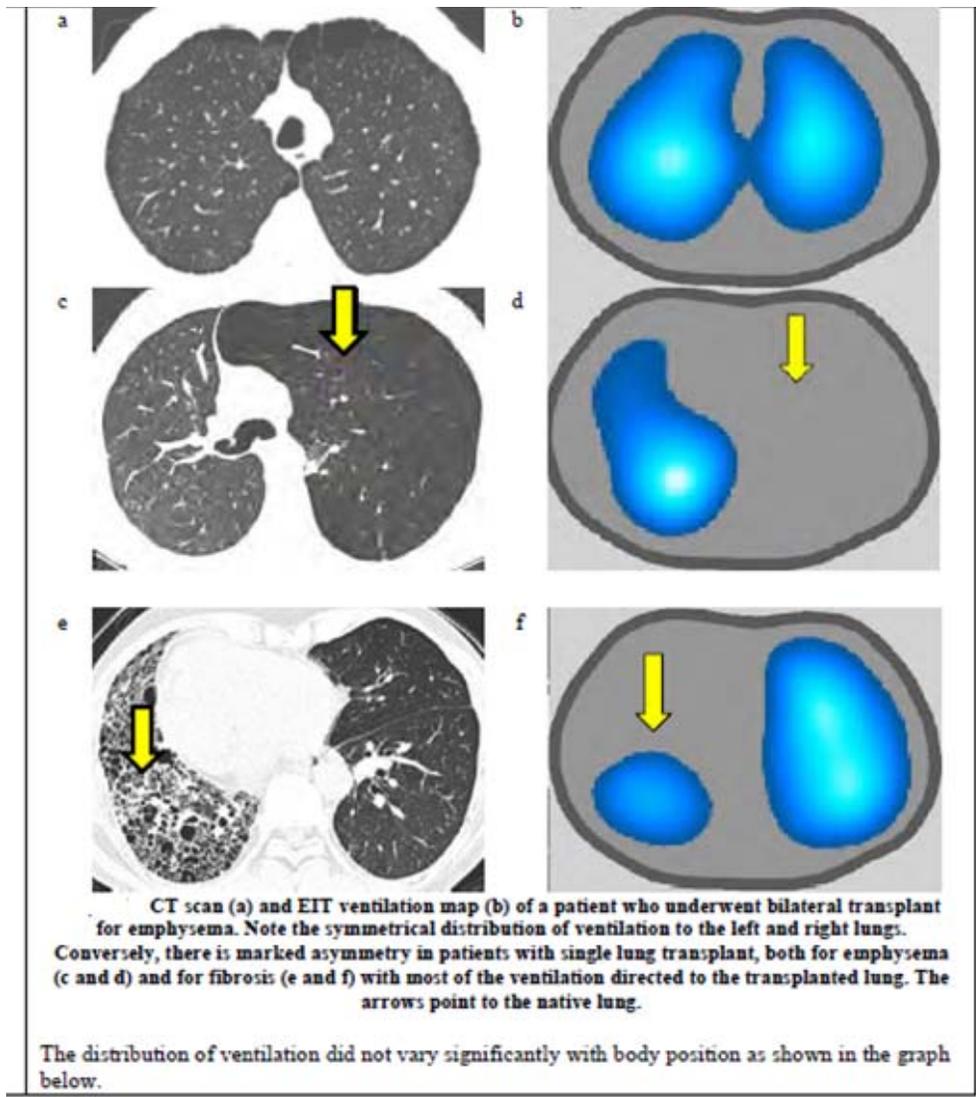
Agreement between EIT and CT was good for the anterior/posterior (bias = -0.01 and limits of agreement = -0.11 to 0.1) as well as for the right/left ROIs (bias = -0.02 and limits of agreement = -0.09 to 0.06) considering a 15-cm thick thoracic slab (7.5 cm above and 7.5 cm below the EIT belt).

2. Assessment of Regional Distribution of Ventilation: Right / Left

Methods: This study assessed 21 patients with lung transplants (11 single lung, 10 bilateral transplant). Regional distribution of ventilation to the right and left lungs was assessed with ENLIGHT during 30 cycles of regular, spontaneous breathing in five different body positions: seated, supine, right lateral, left lateral, and prone. CT scans were performed at total lung capacity in spontaneously breathing patients.

Endpoint: Percent ventilation to the ‘best lung’ according to EIT.

Results: On average, during tidal ventilation and in the supine position, the best lung received $57 \pm 11\%$ in bilateral transplants, $79 \pm 12\%$ in unilateral transplants for emphysema, and $83 \pm 13\%$ in unilateral transplants for fibrosis.

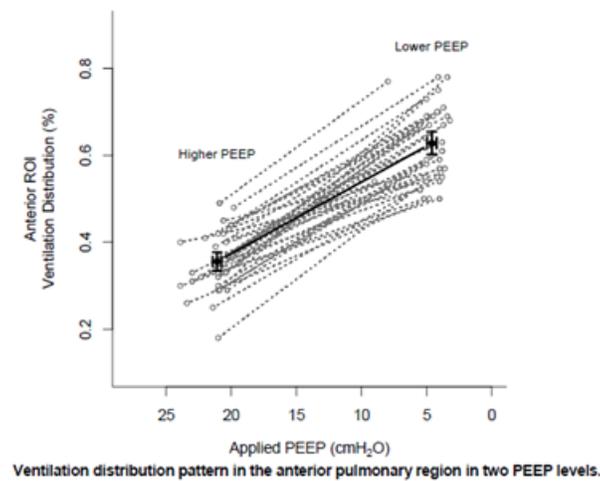


3. Assessment of Regional Distribution of Ventilation: Upper / Lower

Methods: This study was a retrospective analysis of 39 patients who were evaluated for the regional distribution of ventilation to the anterior and posterior halves at different PEEP levels.

Endpoint: The proportion of ventilation to the anterior region, obtained using ENLIGHT, at the highest and lowest PEEP levels available for each patient.

Results: The regional distribution of ventilation to the anterior half of the lung was also $35 \pm 6\%$ during the highest PEEP and $62 \pm 8\%$ ($P < 0.001$) during the lowest PEEP.



Conclusion:

The clinical studies support the use of the subject device as a qualitative tool that provides information of local impedance variation within a cross-section of a patient's thorax. The images in these studies provide qualitative information; however, adequate validation has not been provided for quantitative measures. The clinical studies, support the use of the device as a qualitative tool that should only be used as an adjunct to support the user's assessment of variations in regional air content within a cross section of a patient's lungs based on other clinical information.

Pediatric Extrapolation

In this De Novo request, existing clinical data were not leveraged to support the use of the device in a pediatric patient population.

LABELING

The labeling (User Instructions) meets the requirements of 21 CFR 801.109 for prescription devices. The user instructions include the following:

1. A description and function of all components of the system and instructions regarding how to use each component;
2. A description of how to use the device safely, information on signal acquisition, use of flow sensor, electrode belt and reference electrode;
3. The available images screens and their interpretations;
4. Cleaning instructions for the main unit, which is reusable;
5. Information regarding maintenance and replacement of the main unit;
6. A warning that the device should not be used with defibrillator;
7. Contraindications listing patient comorbidities that would preclude use of the system; and
8. A troubleshooting guide.

RISKS TO HEALTH

The table below identifies the risks to health that may be associated with use of the ventilatory electrical impedance tomograph and the measures necessary to mitigate these risks.

| 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 |

SPECIAL CONTROLS:

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.

BENEFIT/RISK DETERMINATION

The risks of the device are based on nonclinical laboratory studies as well as data collected in the clinical studies described above. The device exhibited an acceptable safety profile in the clinical study that was conducted. No device-related serious adverse events were observed.

The ENLIGHT 1810 risks include incorrect placement of electrode belts on patient, application of belt over broken skin, electrical current leakage from device to patient, use of contaminated components, device failure, incorrect battery replacement, incorrect interpretation of EIT measurements, use of expired Addere, disconnection of reference electrodes during use, incorrect data feed to the device by the user, skewed data due to EMI interference, misinterpretation of data due to nonstandard thorax profile (malformation, surgery etc.), water between electrode belt and patient's skin and incorrect flow sensor placement. Although these device malfunctions or device-related adverse events were not seen in the clinical studies these risks are associated with most devices utilized in critical care settings.

The device is a qualitative tool that compares ventilation differences between the right and left lung. This is useful in a critical care setting for the evaluation of a sudden change in ventilation such as pneumothorax or mucous plugging and in evaluating the respiratory status if there is a sudden change in the patient's clinical status on a ventilator. Risks include incorrect decision making; however, the labeling clearly states that this is not to be used for sole decision-making and will be used in conjunction with other modalities in the critical care setting.

Patient Perspectives

This submission did not include specific information on patient perspectives for this device.

Benefit/Risk Conclusion

In conclusion, given the available information above, the data support that the probable benefits outweigh the probable risks for the ENLIGHT 1810 as an adjunctive tool to other clinical information to support the user's assessment of variations in regional air content within a cross section of a patient's lungs. The device provides benefits and the risks can be mitigated using general controls and the identified special controls.

CONCLUSION

The De Novo request for the ENLIGHT 1810 is granted and the device is classified under the following:

Product Code: QEB

Device Type: Ventilatory electrical impedance tomograph

Class: II

Regulation: 21 CFR 868.1505