June 30, 2023

Bilab
Eung Je Woo, Ph.D.
Chief Technical Officer
5F Ubiquoss Building, 68 Pangyo-ro 255beon-gil, Bundang-gu
Seongnam-si, Gyeonggi-do 13486
Korea, South

Re: K222466
Trade/Device Name: AirTom
Regulation Number: 21 CFR 868.1505
Regulation Name: Ventilatory electrical impedance tomograph
Regulatory Class: Class II
Product Code: QEB
Dated: June 28, 2023
Received: June 28, 2023

Dear Eung Je Woo, Ph.D.:

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

Ethan Nyberg, 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 below.

510(k) Number *(if known)*
K222466

Device Name
AirTom

Indications for Use *(Describe)*
AirTom is a non-invasive, non-radiation medical device that provides information of local impedance variations 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 patients in a professional healthcare facility, whose chest circumference is within the range of 32 ~ 130 cm.

AirTom 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.

510(k) Summary
BiLab's *AirTom®*

1. Submitter's information:

Submitted by	BiLab 5F Ubiquoss Building, 68 Pangyo-ro 255beon-gil Bundang-gu, Seongnam-si Gyeonggi-do 13486, Republic of Korea
Contact person	Eung Je Woo, Ph.D. Chief Technical Officer, BiLab phone: +82-70-4865-0591
Date prepared	June 14, 2023

2. Device information:

Trade name	*AirTom®*
Common/Usual name	Ventilatory electrical impedance tomograph
Classification name	Ventilatory electrical impedance tomograph 21 CFR 868.1505, FDA product code QEB, Class II

3. Predicate device information: AirTom is substantially equivalent to the following:

Manufacturer	Device
TIMPEL S.A.	Enlight 2100 (K211135)

4. Device description

AirTom is a ventilatory electrical impedance tomograph that uses several electrodes (16+1) placed around the patient's thorax to assess regional impedance variations in a lung slice (tomography). It provides only relative measurements about variations in local impedance.

AirTom estimates local impedance variations, occurring in a cross section of the thorax during a breathing cycle, which are linearly related to variations in regional air content within the lungs.

5. Intended Use and Indications for Use

Intended Use: AirTom is intended to be used as a prescription non-invasive, non-radiological ventilatory device that provides an assessment of local impedance variations within a cross section of a patient's thorax.

Indications for Use: AirTom is a non-invasive, non-radiation medical device that provides information of local impedance variations 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 patients in a professional healthcare facility, whose chest circumference is within the range of 32 ~ 130 cm.

AirTom does not measure regional ventilation of the lungs.

6. Summary of technological characteristics compared to predicate device

Both AirTom and the predicate device are prescription devices used by clinicians in similar medical environments, have the same intended use, and are supplied and used, non-sterile.

The AirTom and predicate device systems also have a similar design configuration (composed primarily of a monitor and electrodes) and energy sources. Both systems have a touchscreen that provides user control features. The monitors are connected to electrodes for data measurements.

Ventilatory electrical impedance tomography is employed by both the AirTom and the predicate systems. In the collection of impedance data, the differences between the predicate and AirTom do not raise any questions of safety and effectiveness.

7. Non-clinical performance data provided for substantial equivalence

Technical standards: AirTom was tested and found to comply with the requirements of the technical standards applicable to medical devices (including the predicate device), as listed below.

FDA Guidances: Technical information was also provided in accordance with the recommendations of the FDA Guidances, as listed below.

Testing performed/ information provided	*Tested or Information provided in accordance with Technical Standards and/or FDA Guidances (listed below):*
Shelf life testing – Electrode pads	ANSI/AAMI EC12:2000/(R)2015 Disposable ECG electrodes
Biocompatibility information and testing	*FDA Guidance*: Use of International Standard ISO 10993-1, Biological evaluation of medical devices –Part 1: Evaluation and testing within a risk management process, issued 9-4-20
	ISO 10993-1:2018, Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process
Software information and testing	*FDA Guidance*: Guidance for Industry and FDA Staff: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, issued 5-11-05
Off-the-Shelf (OTS) software information and testing	*FDA Guidance*: Guidance for Industry and FDA Staff: Off-the-Shelf Software Use in Medical Devices, issued 9-27-19
Cybersecurity information	*FDA Guidance*: Draft Guidance for Industry and FDA Staff: Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, issued 10-18-18
Electromagnetic compatibility testing	IEC 60601-1-2 Edition 4.1, Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests
Electrical and Mechanical safety testing, *including*: Basic safety and essential performance testing,	IEC 60601-1:2005 + A1:2012, Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
Usability testing,	IEC 60601-1-6:2010 + A1:2013, Medical Electrical Equipment - Part 1-6: General Requirements For Basic Safety And Essential Performance – Collateral Standard: Usability IEC 62366-1 Edition 1.1 Medical Device-Application of usability engineering to medical devices FDA Guidance: Content of Human Factors Information in Medical Device Marketing Submissions, Draft Guidance, issued 12-09-22
Degrees of protection/ enclosure testing	IEC 60529:2013, Degrees of Protection Provided By Enclosures (IP22)
Patient cable testing	ANSI/AAMI EC53:2013, ECG Trunk Cables and Patient Lead Wires

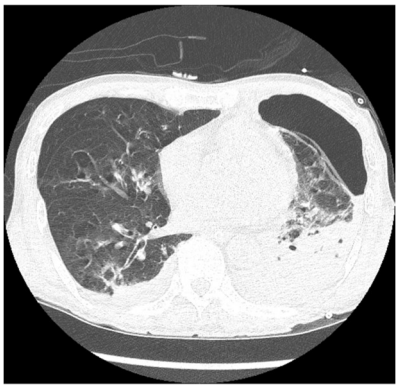
Testing performed/ information provided	*Tested or Information provided in accordance with Technical Standards and/or FDA Guidances (listed below):*
Packaging testing (vibration and shock)	ISTA Procedure 3A: 2018, For packaged products weighing 150 lb (70 kg) or less
Battery testing	IEC 62133-2:2017: Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary lithium cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems
Battery transport testing	ST/SG/AC.10/11/Rev.7 Recommendations on transport of dangerous goods/Manual of tests and criteria/Rev.6/Amend. 1 Part III, subsection 38.3 Lithium metal and lithium ion batteries

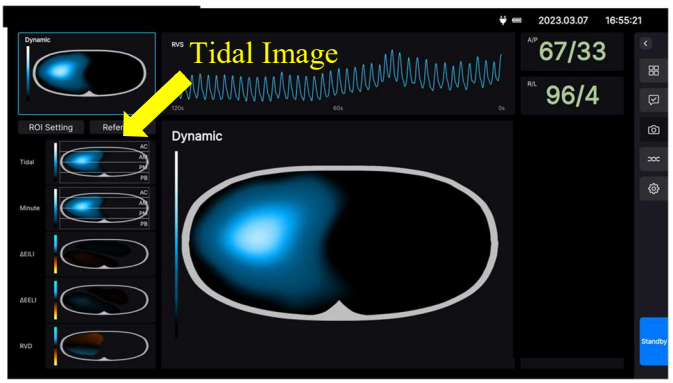
8. Clinical performance data provided for substantial equivalence

A. Comparison of regional ventilation distributions: EIT vs. X-ray CT image

Methods: AirTom was used on six patients during routine clinical practice in ICU. X-ray CT or chest X-ray images were acquired to identify a likely region(s) with a different amount of tidal ventilation. Tidal images from the AirTom device were assessed in terms of regional ventilation in the right (R) and left (L) lungs and also anterior (A) and posterior (P) regions.

Results: Below is a case of a 72-year-old male patient with atelectasis and pneumothorax. The patient was mechanically ventilated. Tidal ventilation in the left lung was only 4% due to atelectasis in the left-posterior/middle region and pneumothorax in the left-anterior/middle region.

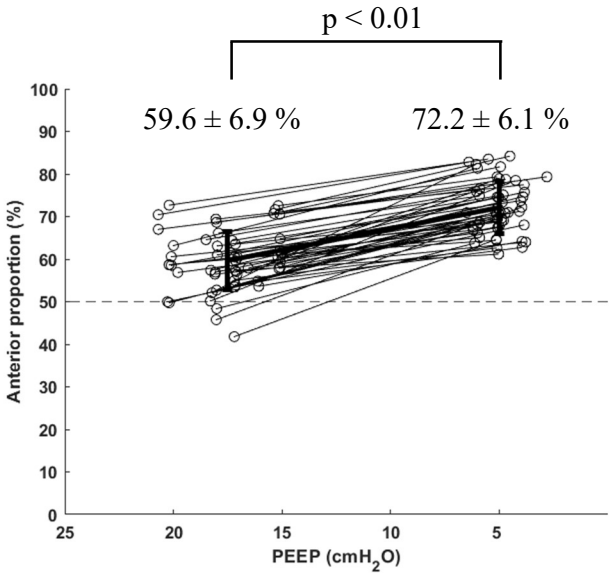




B. Assessment of regional ventilation distributions: Anterior and posterior regions

Methods: This was a retrospective analysis of 53 patients (gender: male and female, age: 3 months ~ 80 years) under general anesthesia during surgery. AirTom monitoring started before induction of anesthesia and continued until the end of operation. Regional distributions of ventilation in the anterior (A) and posterior (P) halves from the 53 patients were evaluated at different PEEP levels.

Results: After induction of general anesthesia, atelectasis occurred in the posterior region (P) in most of the 53 patients in supine position. Due to this atelectasis, tidal ventilation in the anterior region (anterior proportion) increased to an average value of 72.2% at an initial low PEEP value as shown in the figure below. When PEEP was increased to a higher value, some of the collapsed alveoli in the posterior region were successfully recruited to result in larger tidal ventilation in the posterior region. Therefore, tidal ventilation in the anterior region (anterior proportion) was reduced to an average value of 59.6% at a high PEEP value.

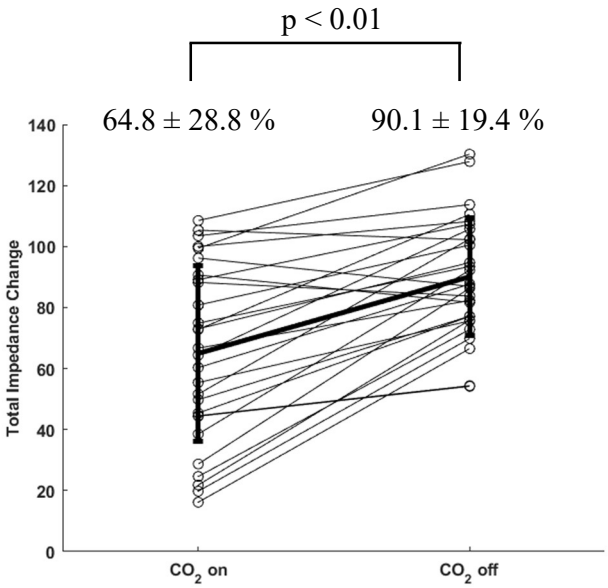


C. Assessment of regional ventilation distributions: With and without pneumoperitoneum

Methods: This was a retrospective analysis of 28 patients (gender: male and female, age: 1 month ~ 80 years) under general anesthesia during laparoscopic surgery with pneumoperitoneum. AirTom monitoring started before induction of anesthesia and continued until the end of operation including time periods before and after CO_2 insufflation. Regional distributions of ventilation were evaluated before and after CO_2 insufflation and also after CO_2 desufflation.

Results: The total impedance changes between two states (CO_2 on and off) from the 28 patients are shown below. The reference time to compute the total impedance change was right after the induction of general anesthesia before CO_2 insufflation.

With pneumoperitoneum by CO_2 on, i.e., after CO_2 insufflation, the total impedance change between end-inspiration and end-expiration decreased on average to 64.8% of the baseline value. After CO_2 desufflation, i.e. CO_2 off, the total impedance change between end-inspiration and end-expiration recovered to 90.1% of the baseline value.



9. Conclusion

On the basis of the clinical and technical information, AirTom is substantially equivalent to the predicate device.

10. Substantial equivalence comparison table

Attributes	Subject AirTom	Predicate ENLIGHT 2100	Explanation of Differences
510(k)		K211135	
Product Classification CFR	868.1505 – QEB	868.1505 – QEB	No difference

Indications for Use	AirTom is a non-invasive, non-radiation medical device that provides information of local impedance variations 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 patients in a professional healthcare facility, whose chest circumference is within the range of 32 ~ 130 cm. AirTom 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.	No difference
Patient population	Adult and pediatric patients, whose thorax perimeter is within the range of 32 ~130 cm.	Adult and pediatric patients, whose thorax perimeter is within the range of 37.5 -134 cm.	AirTom provides Epads for patients with chest circumferences from 32 to 130 cm, while ENLIGHT 2100 provides electrode belts for patient with chest circumferences from 37.5 to 134 cm.
Prescription	Yes	Yes	No difference
Principles 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 difference
Contraindications	defibrillation cardiac pacemakers skin damage open chest wounds hyperhidrosis	High oxygen environment MR environment defibrillation active implanted devices pregnant or lactating women	Similar

	implanted devices body worn devices neonates patients with uncontrolled body movements pregnant or lactating women BMI > 50 Unstable or open thorax		
Environment of Use	Hospital setting	Hospital setting	No difference
Duration of Use	Up to 30 days, with Epad change each 24 hours.	Up to 30 days, with Addere change each 48 hours.	Epad needs to be changed every 24 hours, whereas Addere needs to be changed every 48 hours.
Useful life	AirTom has 5 years of useful life.	ENLIGHT 2100 has 7 years of useful life.	AirTom has a shorter useful life.
Shelf life	Epad has 1 year of shelf life.	Electrode Belt has 1 year of shelf life. Addere has 2 year of shelf life.	No difference (AirTom does not use an Addere.)
Non-sterile	There are no sterile components or accessories.	There are no sterile components or accessories.	No difference
Cleaning methods	Cleaning and disinfection prescribed only for the device. Epad is single patient use.	Cleaning and disinfection prescribed only for the device. Accessories are single patient use.	No difference
Features			
Available sizes	Epad sizes 4XS, 3XS, 2XS, XS, S, M, L, XL	Electrode Belt sizes P0, P1, P2, 4S, 5S, XXS, XS, S, M, L, XL	AirTom offers 8 Epad models, whereas ENLIGHT 2100 offers 11 electrode belt models.
Shape	Monitor-like device, transportable	Monitor-like device, transportable	No difference

Patient contact per ISO 10993-1	Surface contact Intact skin	Surface contact Intact skin	No difference
Performance Characteristics – Bench Test			
Signal-to-noise ratio (SNR)	50dB - 80dB	50dB - 95dB	ENLIGHT 2100 has a higher maximum SNR. AirTom and ENLIGHT 2100 have similar performances in other performance metrics.
Voltage accuracy	90% - 100%	80% - 100%	
Drift	Allan variance (AV_v^2) converges within 100 pV^2	Allan Variance converges to zero (below 100pV^2)	
Reciprocity accuracy	90% - 100%	95% - 100%	
Amplitude response	90% - 104%	90% - 104%	No difference
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%	