June 20, 2023

Thorasys Thoracic Medical Systems, Inc.
Christopher McLean
RA/QA Representative
6560 Avenue de l'Esplanade Suite #103
Montreal, Quebec H2V 4L5
Canada

Re: K221024
Trade/Device Name: tremoflo C2 Airwave Oscillometry System
Regulation Number: 21 CFR 868.1840
Regulation Name: Diagnostic Spirometer
Regulatory Class: Class II
Product Code: PNV
Dated: May 18, 2023
Received: May 18, 2023

Dear Christopher McLean:

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,

Rachana Visaria -S

Rachana Visaria, Ph.D.
Assistant Director
DHT1C: Division of Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia,
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Office of Product Evaluation and Quality
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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221024

Device Name
tremoflo C2 Airwave Oscillometry System

Indications for Use *(Describe)*
The tremoflo C2 Airwave Oscillometry System is intended to measure respiratory system impedance using the Forced Oscillation Technique (FOT). The tremoflo C2 Airwave Oscillometry System is intended for use with pediatric and adult patients 4 years of age or older. The device is designed to be used by pulmonologists, general practitioners, nurses, respiratory therapists, laboratory technologists, medical researchers and similarly trained personnel in hospitals, clinics, and private physician offices.

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

Submitter Information:

Company Name:	THORASYS Thoracic Medical Systems, Inc.
Company Address:	6560 Avenue de l'Esplanade Suite #103
	Quebec, Canada H2V 4L5
Contact Person:	Christopher McLean
Date Summary Prepared:	June 14, 2023
Trade Name:	tremoflo C2 Airwave Oscillometry System
Common/Usual Name:	Respiratory Impedance Measurement Device
Classification Name:	Impedance Measuring Device Utilizing Oscillation Techniques
Product Code:	PNV
Device Class:	Class II
Regulation Number:	21 CFR 868.1840

Predicate Device:

Manufacturer's Name	Brand Name	510(k) Number
THORASYS Thoracic Medical Systems, Inc.	tremoFlo C100 Airwave Oscillometry System	K170185

Device Description:

The tremoflo C2 Airwave Oscillometry System (tremoflo C2) is a portable lung function testing device that implements methods known per the Forced Oscillation Technique (FOT), or oscillometry, to assess lung function in humans. The Forced Oscillation Technique (FOT) is a non-invasive test that provides a full report of lung mechanics per the FOT. In general, the FOT usually consists of superimposing given external multi-frequency sinusoidal excitation small pressure waves (1-3 cmH_2O peak to peak) onto the normal breathing of the patient through the device and then deriving the mechanical properties from the patient's mouth pressure and airflow response while breathing. The main outcome reported by FOT is the mechanical impedance of the respiratory system which is the complex ratio between pressure and airflow at the given excitation frequencies.

The main tremoflo C2 Unit is a lightweight handheld device. It contains electronics, pressure and flow sensors, and the actuator providing the forced oscillations. The tremoflo software is a complete stand-alone software package for patient management, testing, result analysis, and presentation.

During use the operator holds the handheld device using the ergonomic handle while the patient is seated, wearing a standard nose clip and with hands on cheeks. To perform the test, the patient then breathes quietly through the device into a standard single use Pulmonary Function Testing (PFT) filter connected at the front of the C2 Unit via the PFT filter interface. The tremoflo C2 is not intended to be used as a stand-alone diagnostic device.

As compared to the tremoFlo C100 Airwave Oscillometry System predicate (tremoflo C100), the modifications are summarized as follows:

- Changes to the enclosures and the internal hardware and related firmware components such to integrate the two main units of the prior tremoflo C100 version (i.e., the Handheld Unit and the Cradle Unit in the C100) into a single main handheld unit with a new display screen to show the breathing traces and help the user connect their computer to the tremoflo.
- Changes to include Wi-Fi and Bluetooth wireless interfaces and also a USB interface on the main unit for communication to the user's computer instead of the ethernet cable connection in the tremoflo C100
- Changes to the software to accommodate the new communication modes and the hardware/firmware changes.
- Changes to include a rechargeable battery module to allow operation without connections to the mains supply as was required in the C100.

Predicate Product Comparisons:

Indications for Use – No Change

Predicate: **tremoFlo C-100 Airwave Oscillometry System**	**Subject:** **tremoflo C2 Airwave Oscillometry System**
The tremoFlo C-100 Airwave Oscillometry System is intended to measure respiratory system impedance using the Forced Oscillation Technique (FOT). tremoFlo C-100 Airwave Oscillometry System is intended for use with pediatric and adult patients 4 years of age or older. The device is designed to be used by pulmonologists, general practitioners, nurses, respiratory therapists, laboratory technologists, medical researchers and similarly trained personnel in hospitals, clinics, and private physician offices.	The **tremoflo C2 Airwave Oscillometry System** is intended to measure respiratory system impedance using the Forced Oscillation Technique (FOT). The tremoflo C2 Airwave Oscillometry System is intended for use with pediatric and adult patients 4 years of age or older. The device is designed to be used by pulmonologists, general practitioners, nurses, respiratory therapists, laboratory technologists, medical researchers and similarly trained personnel in hospitals, clinics, and private physician offices.

Predicate Product Comparison

Technical Feature/ Specification	**C100 (Predicate)**	**C2 (Subject)**
Fundamental Scientific Technology	Forced Oscillation Technique and Pneumotach per ERS FOT recommendations [1].	Identical
Pneumotach Flow Range	± 2.5 L/s	Identical
Flow Resolution	±1.4 ml/s	Identical
Flow Linearity	± 2% up to 1.0 L/s	Identical
Common Mode Rejection Ratio (CMRR)	Dynamic software compensation signal processing	Identical
Device Load to Patient	1.0 ± 5% $cmH_2O.s/L$ at 1 L/s	Modified: 1.1 ± 5% $cmH_2O.s/L$ at 1 L/s Discussion: The difference in resistance to flow is small and within the potential variation of resistance for bacterial/viral filters that may be used with the tremoflo C100 system and does not raise different questions of safety and effectiveness.
Volume Range	±3 Liters	Identical
Volume Accuracy	<3.0% or 0.050 L (whichever is greater)	Identical
Mouth Pressure (PM)	Piezo Resistive	Identical
Mouth Pressure Linearity	2% of full Scale up to 5 cm H_2O	Identical
Mouth Pressure Resolution	0.0053 cmH_2O (0.0039 mmHg)	0.00265 cmH2O (0.00195 mmHg) Discussion: improved resolution does not raise different questions of safety and effectiveness.
Mouth Pressure Range	± 10 cmH_2O	Modified: ± 5 cmH_2O Discussion: By design the pressure range in FOT measurements never exceeds +/- 5 cm H2O. This is sufficient for human measurements, does not change the performance specifications, and does not raise different questions of safety and effectiveness.
Effective Device Dead Space	35 ml	Identical

Technical Feature/ Specification	C100 (Predicate)	C2 (Subject)
Test Signal / Frequency range	Sinusoidal signal at specific frequencies, between 5-41Hz	Identical
Pseudo-Random Noise (PSRN) Stimulus	5-37 Hz, 7-41 Hz	Identical
Single Frequency Stimuli for a within-breath analysis of respiratory impedance	Can offer 5 to 41 Hz	Identical
Multi-Frequency Stimulus for a with-in breath analysis of respiratory impedance and an estimation of the frequency-dependence of respiratory impedance	5-11-19, 5 to 37 and 7 to 41 Hz	Identical
Energy Type	AC/DC Power adapter 110-240 V / 47-63Hz to 24 V DC	Modified: Integrated rechargeable battery pack, 3.7 volts 5000mAh 18.5Wh, charged via AC/DC Power adaptor 110-240 V to 5 V DC Discussion: In addition to the option of being powered through a medical grade power supply as in the C100, the C2 can also be used in battery operation without the need to connect the device to the mains via a power supply. No effect to functional performance and does not raise different questions of safety and effectiveness.
Compatible Bacterial/Viral Filter and nose clip	Single use, 510(k) cleared PFT Filter (K111587) and nose clip	Identical
Patient Contact/ Biocompatibility	Externally communicating (Indirect), Tissue, limited duration Surface, Skin, limited duration for nose clip and inlet of filter.	Identical. The C2 was tested identically as in the C100 to ensure that the indirect gas contact from their breathing flow pathways present acceptable emissions of VOCs, CO, CO2, Ozone and particulate

Technical Feature/ Specification	C100 (Predicate)	C2 (Subject)
		matter, per ISO-18562-1/2/3, 21 CFR 801.415, and National Air Quality and OSHA limits.
Calculated Impedance Parameters	Total Resistance (Rtot) Inspiratory Resistance (Rinsp) Expiratory Resistance (Rexp) Total Reactance (Xtot) Inspiratory Reactance (Xinsp) Expiratory Reactance (Xexp) R5-R19, R5-R20 AX Fres	Identical
Calculated Breathing Pattern Parameters	Tidal Volume (Vt) Inspiratory Time (Ti) Expiratory Time (Te) Respiratory Duty Cycle (Ti/Ttot) Respiratory Rate (RR) Mean Inspiratory Flow (Vt/Ti) Mean Expiratory Flow (Vt/Te) Ventilation (Ve)	Identical
Breathing Circuit	Includes a pneumotach with a mesh for the flow measurement. A breath-through low resistance Vibrating Mesh (patented) is placed in series with the pneumotach and used to generate the oscillation stimulus during the test.	Modified: includes a pneumotach with a mesh for the flow measurement. A breath-through low resistance mesh (static) is placed in series with the pneumotach at the exhaust. This circuit connects in parallel to a space with a piston which provides the oscillation stimulus during the test. Discussion: Both include a pneumotach and mesh in the breathing circuit, except that the mesh in the C2 is static with the piston being separate in a closed line connected and providing the oscillations to the breathing circuit as opposed to being combined with the mesh in the C100 (vibrating mesh). The flow path and component designs are sufficiently close to that in the predicate device to provide the same input oscillatory excitation profiles and the same respiratory response measurements in both two devices. This does not raise different questions of safety and effectiveness.

Technical Feature/ Specification	**C100 (Predicate)**	**C2 (Subject)**
Test duration	A minimum of 3 measurements with a minimum duration of 20 seconds each and 2 valid breaths minimum per measurements for a total of 60 seconds and 6 breaths minimum per test.	Identical
Electrical Safety Electromagnetic Compatibility	Compliant with • IEC60601-1, Ed. 3.1 • IEC 60601-1-2, Ed 4	Identical for: • IEC60601-1, Ed. 3.1 • IEC 60601-1-2, Ed 4 Additionally tested for immunity to EM energy in RF range per: • AIM 7351731 Rev 2.0 Added compliance to wireless communication standards: • FCC Part 15, Subpart B • coexistence test (EEE/ANSI C63.27-2017) Added compliance to lithium battery standard: • IEC/UL 62133 2012 and IEC 62133-2 :2017 Discussion: these are to ensure compliance to the standards for the added wireless communication and rechargeable battery functions.
Cleaning/ Disinfection	Non-sterile and Non-Critical device with validated and labelled cleaning and low-level disinfection method per FDA Guidance (“Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling”, 2015)	Identical - Validated per FDA guidance as done for the C100

[1]: Oostveen E, MacLeod D, Lorino H, et al. The forced oscillation technique in clinical practice: methodology, recommendations and future developments. Eur Respir J 2003.

Discussion of Technological Differences

The main technology of the device is unchanged in the proposed C2 as compared to the C100 predicate. It involves the same Forced Oscillation Technique (FOT) using the same methods, and the user selected multi-frequency sinusoidal excitation pressure profile specifications (i.e. the waveforms) are the same as in the C100.

The corresponding output and display of pulmonary function characteristics, the patient's respiratory system resistance and reactance at each sinusoidal frequency, the related or other derived outcome parameters (e.g., breathing rate, inspiratory/expiratory volume, etc.) are identical as in the C100 per the same corresponding unchanged Host Software functionalities and algorithms and as was described in the original C100 510(k) aside from the communication protocols and interface changes as described below.

While many of the subcomponents and the breathing circuit were redesigned or re-organized, the C2's performance specifications were re-verified and found to be the same or to be negligibly impacted as compared to the C100. The added wireless communication modes in addition to the predicate's wired communication are for the same functions as the predicate wired mode, which is solely for data and information transfer between the user's computer and the main device unit and do not involve any time critical or time sensitive transfer requirements. These were implemented and tested following telecommunications standards and the FDA guidance Radio Frequency Wireless Technology in Medical Devices. The added battery pack powers the C2 with DC power equivalently as in the C100 via its AC/DC power supply. It was also implemented and tested in compliance with safety standards. The software updates were implemented and tested similarly as in the C100 predicate.

Performance Data:

- Device performance measurement – comparative testing and results as noted above demonstrating equivalent oscillometry performance between the predicate and the proposed C2 device and compliance with the ERS FOT recommendations ([1] as noted above) for the impedance accuracy. The tested parameters included:
    - Resistance Accuracy
    - Reactance Accuracy
    - Impedance Accuracy
    - Intra-Device Total Resistance Repeatability
    - Intra-Device Total Reactance Repeatability
    - Intra-Device Total Impedance Repeatability
    - Tidal Volume Accuracy
    - Intra-Device Tidal Volume Repeatability
- Reproducibility and Repeatability testing demonstrated consistency between the predicate and proposed C2 device with measurement variations < 3.0%.
- Electrical safety and Electromagnetic Compatibility - as per current standards IEC 60601-1:2005+A1:2012 and IEC 60601-1-2:2014+A1:2020 and additionally per AIM 7351731:2017 as noted above.
- Biocompatibility assessment and gas pathway assessment of volatile organic compounds (VOCs), particulates, ozone, CO, and CO2 emission levels per ISO 10993-1:2018, 10993-5:2009, ISO 10993-10:2010, ISO 10993-12:2013, ISO-18562-1/2/3:2017, 21 CFR 801.415, and National Air Quality and

OSHA limits. Contact Type and Duration: Externally communicating (Indirect), Tissue, limited duration (<24 hours); Surface, Intact Skin and Oral Mucosa, limited duration (<24 hours)

- Cleaning/Disinfection Validation Testing - validated as per the FDA guidance; *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling* (2015) and AAMI TIR30:2011.
- Hardware performance validation tests – bench tests conducted to validate that hardware requirements were met.
- Software verification and validation testing – per IEC 62304:2006+A1:2015 and FDA Guidances: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices Document, May, 2005; Off-The-Shelf Software Use in Medical Devices, September 1999; Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, October 2014).

Conclusion:

Based on the above, the tremoflo C2 Airwave Oscillometry System is substantially equivalent to the predicate device.