DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 12, 2017

Thorasys Thoracic Medical Systems, Inc.
% E.J. Smith
Consultant
Smith Associates
1468 Harwell Avenue
Crofton, Maryland 21114

Re: K170185
Trade/Device Name: Tremoflo C-100 Airwave Oscillometry System
Regulation Number: 21 CFR 868.1840
Regulation Name: Diagnostic Spirometer
Regulatory Class: Class II
Product Code: PNV
Dated: August 11, 2017
Received: August 15, 2017

Dear E.J. Smith:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Tara A. Ryan -S
2017.09.12 06:23:08 -04'00'

for
Lori Wiggins, MPT, CLT
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

K170185

Device Name
tremoFlo C-100 Airwave Oscillometry System

Indications for Use *(Describe)*
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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary

tremoFlo C-100 Airwave Oscillometry System

Company Name:	THORASYS Thoracic Medical Systems, Inc.
Company Address:	6560 Avenue de l'Esplanade Suite #103
	Quebec, Canada H2V 4L5
Telephone Number:	514-384-8555 Ext. 133
Fax Number:	514-384-8555
Contact Person:	Sebastien Jutras
Date Summary Prepared:	September 8, 2017
Trade Name:	tremoFlo C-100 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
Medical Graphics Corporation	Resmon PRO FULL	K152585

Device Description:

The tremoFlo C-100 Airwave Oscillometry System (AOS) is a portable lung function testing device that implements methods known per the Forced Oscillation Technique (FOT) to assess lung function in humans. The Forced Oscillation Technique (FOT) is a non-invasive test that requires minimal patient effort and cooperation and 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 tremoFlo C-100 Unit is a lightweight handheld device connected to a cradle unit. The handheld unit contains electronics, pressure and flow sensors, and the actuator providing the forced oscillations which is connected to the cradle unit via a custom cable. The tremoFlo software is a complete stand-alone software package for patient management, testing, and result analysis and presentation.

The tremoFlo C-100 system is easy to transport within a busy clinic or hospital environment. 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 breathes quietly through the device into a standard single use Pulmonary Function Testing (PFT) filter connected at the front of the handheld unit via the PFT filter interface. Like its predicate the tremoFlo is not intended to be used as a stand-alone diagnostic device.

Predicate Product Comparison:

Indications for Use

Thorasys tremoFlo C-100 Airwave Oscillometry System	Resmon PRO FULL K152585
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 Resmon PRO FULL is intended to measure respiratory system impedance using the Forced Oscillation Technique (FOT). Resmon PRO FULL 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	Tremoflo C-100 Airwave Oscillometry System	Predicate: Resmon PRO FULL	Comparison
Fundamental Scientific Technology	Forced Oscillation Technique and Pneumotach per ERS FOT recommendations [1].	Forced Oscillation Technique and Pneumotach per ERS FOT recommendations [1].	Identical
Pneumotach Flow Range	± 2.5 L/s	± 2 L/s	tremoFlo has a 0.5 L/s increased flow range.
Flow Resolution	±1.4 ml/s	±4.6 mL/s	tremoFlo flow resolution is slightly better).
Flow Linearity	± 2% up to 1.0 L/s	± 2% up to 1.5 L/s	the differences are small and still within ranges to provide equivalent performances in both devices per the bench testing.
Common Mode Rejection Ratio	Alternate dynamic software compensation	>60dB over the entire range of forcing	Based on the performance testing the tremoFlo

Technical Feature/ Specification	**Tremoflo C-100 Airwave Oscillometry System**	**Predicate: Resmon PRO FULL**	**Comparison**
(CMRR)	signal processing (derived from Farré et al.[3])	frequencies	compensation provided accurate and reproducible results that are equivalent to those provided by the predicate.
Device Load to Patient	1.0 ± 5% $cmH_2O.s/L$ at 1 L/s	<1 cmH_2O at 1L/s	the difference in resistance to flow is small and within the potential variation of resistance for bacterial/viral filters.
Volume Range	±3 Liters	±2 Liters	tremoFlo has increased volume range.
Volume Accuracy	<3.0% or 0.050 L (whichever is greater)	<3.5% or 0.050 L (whichever is greater)	the tremoFlo has a slightly greater volume accuracy.
Mouth Pressure	Piezo Resistive	Piezo Resistive	Identical
Mouth Pressure Linearity	2% of full Scale up to 5 cm H_2O	±0.050% of full scale up to 2.5 cm H_2O	the differences in pressure linearity are small and still within ranges to provide equivalent performances per the bench testing and meeting the ERS FOT Recommendation [1] of 2 % up to 5 cmH_2O.
Mouth Pressure Resolution	0.0053 cmH_2O (0.0039 mmHg)	0.015 cmH_2O (0.011mmHg)	Tremoflo has better resolution. .
Mouth Pressure Range	± 10 cmH_2O	± 2.5 cmH_2O	the tremoFlo has increased Mouth Pressure Range.
Effective Device Dead Space	35 ml	35 ml	Equivalent.
Test Signal / Frequency range	Sinusoidal signal at specific frequencies, between 5-41Hz	Sinusoidal signal at specific frequencies, between 5-37Hz	tremoFlo provides a sinusoidal signal but with a slightly increased user selectable frequency range
Pseudo-Random Noise Stimulus	5-37 Hz, 7-41 Hz	5-37 Hz	tremoFlo offers a slightly increased frequency range
Single Frequency Stimuli for a within-breath analysis of respiratory impedance	Can offer 5 to 41 Hz	5,6,8 and 10 Hz	tremoFlo offers a slightly increased frequency range with an accuracy equivalent to the predicate as per the performance bench testing. The frequencies are still within the medium frequency range per the ERS FOT Recommendation [1].
Multi-Frequency	5-11-19, 5 to 37 and 7	5-11-19 Hz	tremoFlo offers a slightly

Technical Feature/ Specification	**Tremoflo C-100 Airwave Oscillometry System**	**Predicate: Resmon PRO FULL**	**Comparison**
Stimulus for a with-in breath analysis of respiratory impedance and an estimation of the frequency-dependence of respiratory impedance	to 41 Hz		increased frequency range with an accuracy equivalent to the predicate as per the performance bench testing. The frequencies are still within the medium frequency range per the ERS FOT Recommendation [1].
Reference Resistance of the calibration object	2 cmH2O.s/L	R 2.6 $cmH_2O/L/s$.	The difference of 0.6 $cmH_2O/L/s$ on the nominal resistance value has no impact on the calibration check performance.
Reference Reactance	The slope of X is 0.017 $cmH_2O/L/s^2$	The slope of X is ~0.2 $cmH_2O/L/s^2$	Both devices have similar characteristics and both check for the reactance accuracy upon calibration.
Patient Population	pediatric and adult patients 4 years or older	pediatric and adult patients 4 years or older	Identical
Energy Type	110-240 V / 47-63Hz	100-240 V / 50-60Hz	Equivalent.
Compatible Bacterial/Viral Filter and nose clip	Single use, Given 510(k) cleared PFT Filter (K111587) and nose clip	Single use, Specification of standard Filter, nose clip and optional Mouthpiece as provided by the User	Both devices use a single use filter and nose clip.
Patient Contact/ Biocompatibility	Externally communicating (Indirect), Tissue, limited duration Surface, Skin, limited duration for nose clip and inlet of filter.	Externally communicating (Indirect), Tissue, limited duration Surface, Skin, limited duration for nose clip and inlet of filter.	Only the nose clip and filter come in contact with the patient.
Calculated Impedance Parameters	Total Resistance (Rtot) Inspiratory Resistance (Rinsp) Expiratory Resistance (Rexp) Total Reactance (Xtot)	Total Resistance (Rtot) Inspiratory Resistance (Rinsp) Expiratory Resistance (Rexp) Total Reactance (Xtot)	The provided parameters are identical with the tremoFlo providing additionally AX, which is derived from the reactance curve, and also providing R5-R20 in addition to R5-R19. The performances

Technical Feature/ Specification	**Tremoflo C-100 Airwave Oscillometry System**	**Predicate: Resmon PRO FULL**	**Comparison**
	Inspiratory Reactance (Xinsp) Expiratory Reactance (Xexp) deltaXrs R5-R19, R5-R20 AX fres (frequency when Xtot=0)	Inspiratory Reactance (Xinsp) Expiratory Reactance (Xexp) deltaXrs R5-R19 fres	were substantially equivalent as per bench testing.
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)	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)	The provided parameters are identical with substantially equivalent performances as per bench testing.
Breathing Circuit	Includes a pneumotach for the flow. A breathe-through low resistance Vibrating Mesh (patented) is placed in series with the pneumotach and used to generate the stimulus during the test.	Includes a pneumotach for the flow measurement in series with a low-resistance and high-inertance tube. A woofer loudspeaker, protected by a silicone membrane, is used to generate the stimulus during the test. An air blower flushes fresh air inside the circuit to avoid rebreathing.	No substantial differences. The low dead space offered by the compactness of the tremoFlo does not necessitate a blower to flush air out of the breathing pathway.
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.	One measurement with 5 valid breaths minimum when used for single of multi frequency input waveforms, or from 30 seconds measurement period when used for pseudo-random noise input waveforms.	Similar – tremoFlo minimum of 6 breaths/60 seconds, as compared to in the predicate's 5 breaths minimum (single of multi frequency input) or 30 seconds measurement period (pseudo-random noise input).

Technical Feature/ Specification	Tremoflo C-100 Airwave Oscillometry System	Predicate: Resmon PRO FULL	Comparison
Hardware	tremoFlo Handheld and Cradle Units Laptop or desktop computer	Resmon PRO FULL Head Stand	Both devices provide a user interface and computer that are embedded for the Resmon device, and for the tremoFlo alternately hosted on an external computer.
Electrical Safety Electromagnetic Compatibility	Compliant with ES60601-1:2005 + A2012 (IEC60601-1, Edition 3.1) IEC 60601-1-2:2007	Compliant with ES60601-1:2005 (IEC60601-1, Edition 3.0) IEC 60601-1-2:2007	Equivalent.
Cleaning/ Disinfection	Non-Critical device with validated and labelled cleaning and low-level disinfection method.	Non-Critical device with validated and labelled cleaning and low-level disinfection method.	Equivalent.

[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

Both the Resmon PRO FULL and the tremoFlo C-100 employ Forced Oscillation Technique (FOT) as established in the literature (European Respiratory Society, ERS, Task Force on Respiratory Impedance Measurements to Characterize Lung Function Of The Respiratory System, Oostveen et al., Eur Respir J 2003). The technique relies on the reproducible relationship between pressure and flow of the respiratory system. The bench test data, comparing the performances of the Resmon PRO FULL and the tremoFlo demonstrated substantially equivalent accuracy and repeatability meeting the ERS Task Force FOT Guidelines.

The main difference is that the oscillator technology to impose the pressure waves in the Resmon PRO FULL is an acoustical loudspeaker. The tremoFlo also produces sinusoidal pressure waveforms of known amplitude and discrete frequencies but alternately uses a vibrating mesh oscillator. Both methods induce similar excitations on the patient's airway during normal breathing allowing for computation of impedances in accordance with the ERS Task Force FOT Guidelines.

The tremoFlo also alternately uses a resistive mesh in its flow pathway to provide a certain impedance to prevent that the produced oscillations leak outside of the flow pathway. This ensures that the resulting oscillatory flow and pressure signals have a sufficient signal-to-noise ratio to ensure repeatability and accuracy of measurements. Comparatively the Resmon PRO FULL uses a high inertance tube instead of the resistive mesh to keep sufficient flow and pressure signals in the flow pathway. As shown by the performance results, both breathing circuits are substantially equivalent in meeting the recommended ERS Task Force FOT Guidelines.

While the Resmon PRO FULL is a standalone device with integrated touch display and computing as compared to the tremoFlo which is used in conjunction with a computer to host the software and provide display and review management of the measurement results, both are substantially equivalent with respect to the computer display type of technology used.

Performance Data:

- Device measurement performance –testing to compare the performance specifications (impedance and breathing pattern parameters) between the predicate and the tremoFlo device.
- Reproducibility and Repeatability - 3 units were tested with repeated measurements and the results demonstrated consistency between the different devices and for multiple measurements with variations < 2.5%. This was within performance specifications.
- PFT filter (K111587) validation for pediatric use – testing/validation of dead space, resistance, port sizes and filtration efficiency.
- Electrical safety and Electromagnetic Compatibility - as per standards AAMI ES60601-1:2005 +A2012 and IEC 60601-1-2 ed. 3.0 (2007).
- Biocompatibility testing - Based upon ISO 10993-1 and the related FDA Guidance; *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"* (2016), testing was performed to verify acceptable VOC, Carbon Monoxide, Carbon Dioxide, Ozone and particulate matter (Particulate Matter 2.5 microns) levels from the breathing pathways of the device per the indirect patient contact mode.
- Cleaning/Disinfection Validation Testing - validated as per the FDA guidance; *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling* (2015).
- Hardware performance validation tests – bench test conducted to validate that hardware requirements are met.
- Software verification and validation testing – Unit, integration, system, and validation tests (per 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).

Clinical Study:

No clinical study was conducted.

Conclusion:

Based on the above, the tremoFlo C-100 Airwave Oscillometry System is as safe and as effective as the predicate, Resmon PRO FULL.