DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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November 4, 2016

Medical Graphics Corporation
% Amy Fowler
Consultant for Medical Graphics
350 Oak Grove Parkway
St. Paul, Minnesota 55127

Re: K152585
Trade/Device Name: Resmon PRO FULL
Regulation Number: 21 CFR 868.1840
Regulation Name: Diagnostic Spirometer
Regulatory Class: Class II
Product Code: PNV, BZC
Dated: May 19, 2016
Received: May 23, 2016

Dear Ms. Fowler:

This letter corrects our substantially equivalent letter of June 24, 2016.

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 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 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 yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Tina Kiang, Ph.D.
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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 below.

510(k) Number *(if known)*
K152585

Device Name

Resmon PRO FULL

Indications for Use *(Describe)*
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.

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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Date Prepared November 1, 2016

Official Contact: Jim Purdie
350 Oak Grove Parkway
St Paul MN 55127 USA
Phone: 651.766.3358
Fax: 651.484.8941

Proprietary or Trade Name: Resmon PRO FULL

Common/Usual Name: Device for measuring respiratory impedance

Classification Name: PNV Diagnostic Spirometer
21 CFR 868.1840, Class II
BZC Calculator, Pulmonary Function Data
21 CFR 868.1880, Class II

Predicate Device: Carefusion MasterScreen IOS 510(k) K101873

Device Description:
Resmon PRO FULL is a device for the assessment of the mechanical impedance based on the Forced Oscillation Technique (FOT).

FOT is a non-invasive lung function test for measuring the mechanical properties of the respiratory system. It consists in applying very small pressure oscillations (1-3 cmH_2O peak-to-peak) of a given frequency/frequencies (usually below 40Hz) at the patient's mouth while she/he is breathing normally. During the test, the device measures pressure at the mouth and airflow to calculate respiratory impedance in real-time. Impedance is the complex ratio between pressure and airflow estimated at the frequency of the stimulating waveform. Common stimulating waveforms range from a simple sinusoid wave to a composite of different frequencies or impulses. The first approach is utilized for tracking swift changes in respiratory impedance. Examples of this include breath changes in lung mechanics or outcome measurements of specific interventions. The latter is used to assess the frequency dependency of impedance (related to the degree of lung heterogeneity) and identify the parameters of mathematical models of the respiratory system.

FOT allows for measurement during a patient's normal breathing pattern, with no forced effort required, making it suitable for monitoring non-cooperative patients, such as elderly patients, children or very severely ill patients with limited forced capacity. The test is usually performed with the subject seated, wearing a nose-clip (to prevent airflow leaks from the nose during normal breathing) and with hands on cheeks (to prevent the shunt of the pressure stimulus in the upper airways). The device is not intended to be used as a stand-alone diagnostic device.

Resmon PRO FULL consists of a main unit which has been designed to be used stand-alone, without the need of any personal computer, and an adjustable holder with a clamp to fix such unit to a table/desk and to regulate its height and orientation to the patient during an FOT test.

Specifications for the device can be found in the table of comparison below.

Intended Users:
Clinicians

Indications for Use:
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.

Device Comparison

Table 1 - Comparison with the MasterScreen IOS K101873

Technical feature/specification	MasterScreen IOS K101873	Resmon PRO FULL
Fundamental Scientific Technology	Forced Oscillation Technique / pressure to flow conversion technique (pneumotach handle)	Forced Oscillation Technique and Pneumotach
Pneumotach Flow Range	0-20 LPS (tidal breathing/spirometry)	0-2 LPS (tidal breathing)
Flow Resolution	±10 mL/s	± 4.6 mL/s
Flow Accuracy	Up to 12 L/s ± 2% or ± .2 L/s (whichever is greater)	Up to 1.5 L/s ± 2%
CMRR	60 dB at 50 Hz	> 60dB over the entire range of forcing frequencies
Flow Resistance	0.5 cmH_2O at 10 L/s	< 1 cmH_2O at 1L/s
Volume Range	±20 liters tidal breathing/spirometry	±2 liters
Volume Accuracy	0.5 to 8 L: ± 3% or ± 0.05 L (whichever is greater)	<3.5% or 0.050 L (whichever is greater)
Mouth Pressure (PM)	Piezo Resistive	Piezo Resistive
Mouth Pressure Accuracy	±2%	±0.05% of full scale
Mouth Pressure Resolution	.023 (mmHg)	.011 mmHg
Test Signal	Impulse of alternating direction of all frequencies between 0-100Hz.	Sinusoidal signal at specific frequencies, between 5-37Hz
Pulse Interval	.1 to 6 seconds	Not Available
Impulse length	45 ms	Not Available
Frequency Range	0 – 100Hz	5-37 Hz
Single Impulse Power Spectrum	-20dB at 40 Hz	Not Applicable
Pseudo-Random Noise (PSRN) Stimulus	Not available	5-37 Hz
Single Frequency Stimuli for a within-breath analysis of respiratory impedance	Not available	5, 6, 8, 10 Hz
Multi-Frequency Stimulus for a within-breath analysis of respiratory impedance and an estimation of the frequency-dependence of respiratory impedance	5-20 Hz	5-11-19 Hz

Technical feature/specification	MasterScreen IOS K101873	Resmon PRO FULL
Reference Resistance	2 $cmH_2O/L/s$ (accuracy <±2%)	The resistance of the calibration object has an approximate value of R = 2.6 $cmH_2O/L/s$. Actual values are identified on the calibration object label.
Reference Reactance	Not available	The reactance of the calibration object increases with frequency. The slope of X is ~0.2 $cmH_2O/L/s^2$
Patient Population	MasterScreen IOS can be used for adult, geriatric and pediatric population	Resmon PRO FULL can be used in pediatric and adult patients 4 years of age or older
Energy Type	100-240 V / 50-60Hz	100-240 V / 50-60Hz
Accessories	Single use, Filter, nose clip and optional Mouthpiece Provided by the user	Single use, Filter, nose clip and optional Mouthpiece Provided by the user
Patient contact	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
Calculated Impedance Parameters	Total Resistance (Rtot) Inspiratory Resistance (Rinsp) Expiratory Resistance (Rexp) Total Reactance (Xtot) Inspiratory Reactance (Xinsp) Expiratory Reactance (Xexp) deltaXrs R5-R20	Total Resistance (Rtot) Inspiratory Resistance (Rinsp) Expiratory Resistance (Rexp) Total Reactance (Xtot) Inspiratory Reactance (Xinsp) Expiratory Reactance (Xexp) deltaXrs R5-R19
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)
Breathing Circuit	Includes a pneumotach for the flow measurement in series with an elbow connector and a screen resistance at the opposite end. A woofer loudspeaker, protected by a screen, is 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.
Hardware	IOS Head Trolley or Stand Accessories Desktop/Notebook	Resmon PRO FULL Head Stand Accessories

Comparison to Predicate Device:
The Resmon PRO FULL is viewed as substantially equivalent to the predicate device because:
The Resmon PRO FULL uses the same technology and has similar indications for use. There are no differences between the Resmon PRO FULL and the predicate with questions about safety or efficacy.

Indications – The indications for use are similar. The subject device utilizes the impedance oscillatory technique and is to be used in combination with other approved pulmonary diagnostic methods if used for diagnostic purposes. The predicate device incorporates spirometry (used for diagnostic purposes) and the impedance oscillatory technique. The proposed indications reflect the usefulness of the subject device in the assessment and measurement of the respiratory system impedance per the published guidance. Overall, the indications for use are similar when comparing the same forced oscillation technology. The differences do not affect substantial equivalence.

Prescriptive – The Resmon PRO FULL and predicate are prescription devices.

Design and Technology – The Resmon PRO FULL and predicate have equivalent design features and technology

Performance and Specifications – The Resmon PRO FULL has equivalent specifications of performance as compared to the predicate. There are some measured parameters that are different for example R5-19 for the subject device vs. R5-20 for the predicate. The difference is which frequencies are subtracted. These are relative and reference measurements not for diagnostic use.

Compliance with Standards – The Resmon PRO FULL conforms to the following standards:

- ANSI AAMI ES 60601-1:2005 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2007 Collateral standard: Electromagnetic Compatibility - Requirements and Tests

Resmon PRO FULL also complies with ERS Forced Oscillation Technique Guidelines.

Patient Population – The Resmon PRO FULL and MasterScreen IOS are indicated for pediatrics and adults

Environment of Use – Resmon PRO FULL and MasterScreen IOS are for clinics, hospitals and doctor's offices.

Differences –There are no differences between the subject device and the predicate device that raise any new safety and efficacy concerns.

Summary of Performance Testing
We performed the following tests.

Non-clinical:

- Hardware Verification
- Software and System Verification and Validation
- Compliance with ANSI AAMI ES 60601-1:2005
- Compliance with IEC 60601-1-2:2007

Biocompatibility:
Based upon ISO 10993-1 and G95-1 the testing for hardware is VOCs, Carbon Monoxide, Carbon Dioxide, Ozone and particulate matter ($PM_{2.5}$) detection. The patient contact is Externally

Communicating, Tissue, Limited Duration (<24 hours). There are no direct patient contacting parts to this device.

Comparative:
Comparative testing was done with the subject device and the predicate across the range of parameters and performance specifications. The study objectives were:

- To establish the level of reproducibility and repeatability of the Resmon PRO FULL measured parameters
- To test the Resmon PRO FULL measured parameters compared with those provided by the predicate device, MasterScreen IOS

The following parameters were tested:

- Impedance parameters
  - Rinsp: inspiratory resistance
  - Rexp: expiratory resistance
  - Rtot: total resistance
  - Xinsp: inspiratory reactance
  - Xexp: inspiratory reactance
  - Xtot: total reactance
  - ΔXrs: difference between Xinsp and Xexp at 5 Hz
  - R_{519}: difference between Rinsp at 5 Hz and Rinsp at 19 Hz
- Breathing pattern parameters
  - Ti: inspiratory time
  - Te: expiratory time
  - Ti/Ttot: respiratory duty cycle
  - RR: respiratory rate
  - Vt: Tidal volume
  - Vt/Ti: mean inspiratory flow
  - Vt/Te: mean expiratory flow
  - Ve: minute ventilation

Reproducibility and Repeatability: Multiple units were tested and the results demonstrated consistency between the difference devices and for multiple measurement with variations < 4%. This was within performance specifications.

Animal
None

Clinical
None

Substantial Equivalence Conclusion-
Based on the above, we conclude that the Resmon PRO FULL is substantially equivalent to the predicate device in indications for use, patient population, and environment for use, technology characteristics, specifications / performance and compliance with the same international standards