DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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June 29, 2015

Vitalograph Ireland Ltd.
Tom J. Healy
Regulatory Affairs/QA Manager
Gort Road Business Park,
Ennis, Co Clare
IRELAND

Re: K142812
Trade/Device Name: Vitalograph Model 6800 Pneumotrac
Regulation Number: 21 CFR 868.1840
Regulation Name: Diagnostic spirometer
Regulatory Class: II
Product Code: BZG
Dated: May 27, 2015
Received: May 29, 2015

Dear Mr. Healy:

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" (21CFR 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

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
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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: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K142812

Device Name
Vitalograph Model 6800 Pneumotrac

Indications for Use *(Describe)*
The device is a spirometer which measures patient respiratory parameters including FVC, FEV1, FEV6, PEF, MVV and VC. The Vitalograph Pneumotrac is a desktop spirometer designed for lung function testing for use on adults and pediatrics, 5 years and older, in a variety of environments such as hospital wards, health centers and private homes under the supervision of a healthcare provider.

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)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510K Summary

as required by 21 CFR 807.92

1. Company Information:
   Name: Vitalograph (Ireland) Ltd
   Address: Gort Road Business Park, Ennis, Co Clare, Ireland.

   Tel: +353656864100
   Fax: +353656829289.

2. Contact Person / Official Correspondent:
   Mr. Tom J Healy
   Regulatory Affairs / Quality Assurance Manager

3. Date prepared:
   19th June 2015.

4. Device Trade Name:
   Vitalograph Model 6800 Pneumotrac

5. Common / Usual name:
   Vitalograph Pneumotrac,

6. Classification number:

   Classified per 21 CFR 868.1840.
   Part 868 – Anesthesiology Devices, Subpart B--Diagnostic Devices
   Class 2 Diagnostic Spirometer
   Product Code BZG.

7. Predicate Device:

Manufacturer	: Vitalograph
Device Name	: Model 2120
510(k) No	: K100687, Class 2, Product Code BZG.

8. Description of Device:

The intended use of the Vitalograph Pneumotrac desktop spirometer, which connects to Vitalograph Model 7000 Spirotrac software, ref 510(k) K141546, shall provide a USB-powered desktop spirometer for creating, adding and recalling subjects and performing Spirometry testing on those subjects to aid in the measuring the effect of lung disease on pulmonary function.
Spirometry is in the simple assessment of respiratory function through the measurement of dynamic lung volumes.

Its primary functions are;

1. Standalone spirometric measures using single breath or multiple-breath testing techniques, display and record lung volumes and flow rates (including FVC, MVV, VC) and it's subdivisions,
2. Display a single subject's demographic data entered by the user.
3. Produce reports

In a clinical setting, the measurements obtained from a lung function test form part of the various findings of a physician in the detection, diagnosis and monitoring of chest diseases.

9. Indications for Use:

The device is a spirometer which measures patient respiratory parameters including FVC, FEV1, FEV6, PEF, MVV and VC. The Vitalograph Pneumotrac is a desktop spirometer designed for lung function testing for use on adults and pediatrics, 5 years and older, in a variety of environments such as hospital wards, health centers and private homes under the supervision of a healthcare provider.

10. Technological Characteristics

The characteristics of the Pneumotrac are similar to those of the predicate device listed in comparison table below. The similarities are:

- Identical operating principle
- Identical spirometry parameters measured
- Both the subject and predicate devices comply with international performance standards including electrical safety {IEC 60601-1}, EMC {IEC 60601-1-2} and performance bench tests {ISO 23747, ISO 26782, ATS/ERS}
- Sharing of Identical patient interface accessories

The primary differences between the Vitalograph Model 6800 and the predicate devices is that the predicate operates as a portable spirometer and the Model 6800 is a desktop spirometer.

The indications for use for the Vitalograph Pneumotrac now include pediatric population in line with the updated FDA guidance. The Model 6800 has the same indications for use, including pediatric population, as the Model 7000 as cleared under K141546. No new testing was required for this revised indication for use. No new risks have been introduced as a result of pediatric population inclusion. The device complies with the existing international performance standards to cater for all population groups.

All of the device materials were previously cleared in the predicate (K100687) and create no new risk profiles. The Model 7000 Spirotrac which connects to the Pneumotrac device was previously cleared. Materials used in the Vitalograph 6800 Pneumotrac are identical to those used in previously cleared devices. Thus separate biocompatibility testing was not performed for the subject device.

Risks have been evaluated and the connectivity / communication by model 6800 Pneumotrac has been validated with the Vitalograph Model 7000 Spirotrac software. This validation is on file.

The operating principle, measuring range, application and use are unchanged. Packaging and labelling has been updated to conform to current regulatory requirements but otherwise remains substantially unchanged. Precautions, warnings, contra-indications and software functionality remain unchanged.

Parameter	Vitalograph model 6800 Pneumotrac	Predicate Device – Vitalograph Model 2120 (K100687)
Volume Range	0-10 Liters	0-10Litres
Max Flow Range	0-16 Liters / second	0-16 Liters / second
Back Pressure	Less than 0.1kPa/L/s	0.1kPa/L/s
Accuracy FEV1	+/- 3%	+/- 3%
Accuracy FEV6	+/- 3%	+/- 3%
Accuracy PEF	+/-5%	+/-5%
Calibration	Using calibration syringe	Using calibration syringe
Technology	Fleisch Pneumotachograph	Fleisch Pneumotachograph
Set Predicted / reference values	Yes	Yes
Memory Type / Storage:	Uses Spirotrac database. {K141546}	On-board or connection to Spirotrac database {K141546}
Sounds	Audible beeps emitted whilst performing a test, for incentives.	Audible beeps emitted whilst performing a test, for incentives.
Communication	USB	USB
Download to P.C	Yes. Downloads to Spirotrac {K141546}	Yes. Downloads to Spirotrac {K141546}
To be serviced	Yes, Has Service Manual.	Yes. Has Service Manual.
Connection to external printer	Yes, via Spirotrac {K141546}	Yes. Direct or via Spirotrac {{K141546}}
Internal printer	No	No
Battery Type	USB Power	USB Power and 3.7V Li-ion

power		Battery.
Dimensions	183x105x70mm	160x100x45mm
Weight	0.45Kg	0.23Kg
Material Type	ABS plastic Body, Silicone Rubber, Stainless Steel, Aluminum, TPX plastic	ABS plastic Body (identical), Silicone Rubber(identical), Stainless Steel(identical),
Biocompatibility	No new testing required. All materials previously cleared in K100687 & K925085.	
Operating Temp:	10-40°C. {At least 17-37°C required per ATS 2005}	10 to 40°C {At least 17-37°C required per ATS 2005}
Storage Temp	0 - 50 °C	0 - 50 °C
Humidity	10 - 95% relative humidity	10 - 95% relative humidity
Performance Standards {bench tests}	ATS ERS 2005, ISO 23747:2009 for PEF {formerly EN13826:2003}. EN ISO 26782:2009 ISO 10993-1 Fourth Edition	ATS ERS 2005, ISO 23747:2009 for PEF {formerly EN13826:2003}. EN ISO 26782:2009 ISO 10993-1 Fourth Edition
Compliance:	IEC / EN 60601 {EN 60601-1-1 and EN 60601-1-2}	IEC / EN 60601 {EN 60601-1-1 and EN 60601-1-2}
Interface with user	Spirotrac {K141546}	On-board Button Keypad / touchscreen display or via Spirotrac {{K141546}}
Regulatory	FDA - 510(k) CE {0086} Class 2a	FDA - 510(k) CE {0086} Class 2a
Product Code, Class, CFR	BZG, Class 2, 868.1840	BZG, Class 2, 868.1840
Warranty	1 Year	1 Year
Patient interface accessories	Model 2820 BVF Mouthpiece (K942779) {Class 2 with an active device listing}.	Model 2820 BVF Mouthpiece (K942779) {Class 2 with an active device listing}. Model 2020 SafeTway Mouthpiece {Class 1 with an active device listing}.

Indications for Use	The device is a spirometer which measures patient respiratory parameters including FVC, FEV1, FEV6, PEF, MVV and VC. The Vitalograph Pneumotrac is a desktop spirometer designed for lung function testing for use on adults and pediatrics, 5 years and older, in a variety of environments such as hospital wards, health centers and private homes under the supervision of a healthcare provider.	The device is a battery operated spirometer which measures three basic patient respiratory parameters {FVC, MVV and VC}. The model 2120 is a hand held spirometer designed for lung function testing in a variety of environments such as hospital wards, health centers and private homes. The model 2120 can be configured as a stand-alone spirometer or connected to a printer.

The Vitalograph Model 6800 Spirotrac underwent validation bench testing to ensure performance according to its specifications against current standards. These tests included performance testing against international standards such as

- ISO 26782{Anesthetic and respiratory equipment -- Spirometers intended for the measurement of time forced expired volumes in humans},
- ATS/ERS 2005 {ATS/ERS Task Force: Standardization of Lung Function Testing} and
- ISO 23747 {Anesthetic and respiratory equipment -- Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans}.
- IEC 60601-1

Biocompatibility was reviewed during the risk management process. Separate biocompatibility testing was not carried out as all materials we previously cleared in earlier submissions including K100687 and K925085.

Validation of the interfaces with model 7000 Spirotrac {K141546} was performed to ensure that the integrity of the information is maintained and that the information may be successfully downloaded and stored within the Spirotrac database.

All tests and validations demonstrated satisfactory results. Evidence of successful completion of tests and validations has been provided with this submission.

11. Conclusion:

Based on the above, including the successful completion of all device testing Vitalograph conclude that Vitalograph model 6800 Pneumotrac is as safe and as effective as the predicate devices. No new issues of safety or effectiveness have been introduced as a result.