DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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September 3, 2014

Vitalograph (Ireland) Ltd.
C/O Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K141546
Trade/Device Name: Vitalograph Model 7000 Spirotrac
Regulation Number: 21 CFR 868.1840
Regulation Name: Diagnostic Spirometer
Regulatory Class: II
Product Code: BZG
Dated: August 15, 2014
Received: August 19, 2014

Dear Mr. Job:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,
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)*
K141546

Device Name
Vitalograph Model 7000 Spirotrac

Indications for Use *(Describe)*
The Vitalograph Model 7000 Spirotrac is intended for use by or on the order of a physician in a hospital or clinic setting. The product is designed for use on both adult and pediatric patients. The device is a PC based software application which is intended to be used as a spirometer or connect to compatible Vitalograph or third party devices to acquire, view, store and print the device output.

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)*

FDA

Anya C. Harry -S
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This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Office of Chief Information Officer
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PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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:
   2nd July 2014.

4. Device Trade Name:
   Vitalograph Model 7000 Spirotrac

5. Common / Usual name:
   Vitalograph Spirotrac,

6. Classification number:

   Class 2 Spirometer as classified per 21 CFR 868.1840.
   Product Code BZG.

7. Predicate Device:

Manufacturer	: Welch Allyn
Device Name	: CardioPerfect Workstation Software
510(k) No	: K082478, Class 2, Product Code BZG.
Manufacturer	: MIR
Device Name	: Spirodoc
510(k) No	: K103530, Class 2, Product Code BZG.

8. Description of Device:

   Spirotrac shall provide a secure PC based medical device software application for creating, adding and recalling subjects and performing Spirometry testing on those subjects. Spirotrac will also link to compatible third party devices to read and display the output from these devices to allow the information to be retained with the subject

Spirotrac will integrate and read / display information from Pulse Oximetry devices, Blood Pressure and Weight measurements devices, and ECG test devices.

Its primary functions are:

1. Spirometry measurements using single breath and multiple-breath testing techniques, the display and recording of measured lung volumes and flow rates (including VC, FIVC, FVC) and it's subdivisions, The unit also allows for the measurements of Inspiratory and Expiratory Flow rates (PEF, FEFx, etc), indirect measures (e.g. MVV) and Pre-post testing (e.g. Challenge, work shift).
2. Record subject demographic data as input.
   Interact with existing Vitalograph and compatible third party devices via standard PC communication methods for download of data for storage within the Spirotrac database.
3. Navigation is allowed via the use of a standard PC keyboard and mouse or touchscreen.

9. Indications for Use:

The Vitalograph Model 7000 Spirotrac is intended for use by or on the order of a physician in a hospital or clinic setting. The product is designed for use on both adult and pediatric patients. The device is a PC based software application which is intended to be used as a spirometer or connect to compatible Vitalograph or third party devices to acquire, view, store and print the device output.

10. Technological Characteristics

The primary difference between the revised Vitalograph Model 7000 Spirotrac and the predicate devices is the inclusion of the weighing scales as a compatible third party devices. The predicates all measure spirometry with optional ECG, Blood Pressure, Weight and Pulse Oximetry connectivity.

The connectivity to other compatible devices is to allow data to be downloaded from the other devices via a cable or wireless connection, in lieu of manual data entry which can still be performed within Spirotrac.

Connectivity includes a wired / wireless connection to devices to allow downloading of data into the Spirotrac database. Risks have been evaluated and the connectivity / communication with other devices have been validated with the Vitalograph Model 7000 Spirotrac software. This validation is on file for all devices.

	Welch Allyn CardioPerfect Workstation Software, K082478	Spirotrac Model 7000	MIR Spirodoc, K103530
Spirometry - acquire, view, store and print measures and waveforms of pulmonary function	Yes	Yes	Yes
ECG waveforms - view, store, print	Yes	Yes	No
ECG waveforms - acquire	Yes	Yes, From compatible device.	No
ECG waveform- view, store, print	Yes	Yes	No
ECG Interpretation via algorithms	Yes	Yes	No
Ambulatory Blood Pressure - retrieve, view, store and print patient ambulatory blood pressure history	Yes	Yes, from compatible device.	No
Spot Oximetry download, view.	No	Yes, From compatible device.	Yes
Weight	Manual entry	Manual entry or download via connection to compatible device	No
Microsoft windows Operating Systems Supported:	Yes	Yes	Yes
Database:	MS SQL Server	MS SQL Server	MS SQL Server
Where used	Hospital, Clinic	Hospital, Health centre, primary care practices and clinics	Physician or patient under prescribed us of a physician
Networked operation	Yes	Yes	Yes
Subject Management: Demographic Entry, Maintenance and Deletion	Yes	Yes	Yes
Report Printing	Yes	Yes	Yes
Spirometry testing	Yes	Yes	Yes
Trending Graphs for Spirometry Results	Yes	Yes	Yes

Spirometry Predicted Value Equations	Yes	Yes	Yes
Population Group Management	Yes	Yes	Yes
Data Import/Export	Yes	Yes	Yes
Subject and Spirometry Data Export	Yes	Yes	Yes
Manual data entry of results	Yes	Yes	Yes
Data export via Email	Yes	Yes	Yes
Database Management	Yes	Yes	Yes
Colour Display	Yes	Yes	Yes
Population groups	Adult, Paediatric	Adult, Paediatric	Yes
Target Population	Adult & Paediatric	Adult & Paediatric	Spirometry - Adult & paediatric Oximetry – All ages
Communication	Wireless, USB, Serial,	Bluetooth, USB,	Bluetooth, USB
Storage	Dependent on storage media	Dependent on storage media	
Sterile	No	No	No
Regulatory (USA):	FDA - 510(k) Class 2 { K082478}	FDA - 510(k) Class 2	FDA - 510(k) Class 2 {K103530}
Indications for Use	The CardioPerfect Workstation software and associated accessories are indicated for the acquisition, analysis, formatting, display, printing and storage of certain physiologic signals, as identified below, for the purpose of assisting the clinician in the diagnosis and monitoring of various diseases and/or treatment regimens. The CardioPerfect Workstation software also provides non-diagnostic functions such as patient management, data security, search tools for patient and/or test records and support for exporting data to Electronic Medical Record systems.	The Vitalograph Model 7000 Spirotrac is intended for use by or on the order of a physician in a hospital or clinic setting. The product is designed for use on both adult and pediatric patients. The device is a PC based software application which is intended to be used as a spirometer or connect to compatible Vitalograph or third party devices to acquire, view, store and print the device output.	The Spirodoc Spirometer and pulse oximeter is intended to be used **by** a physician or by a patient under the prescribed use of a physician. The device is intended to test lung function and can perform spirometry testing in adult and pediatric patients, excluding infants and neonates, and oximetry readings in patients of all ages.

	The CardioPerfect Workstation and associated accessories are intended for use by or on the order of a physician in a hospital or clinic setting. The product is designed for use on both adult and pediatric patients, subject to any specific contraindications identified below. **Stress Electrocardiograph** - **Intended Use** Using the optional ECG module and associated accessories the user can acquire, view, store and print ECG waveforms. **Resting Electrocardiograph** - **Intended Use** The same as defined for stress ECG plus the ability to use optional algorithms (MEANS) to generate measurements, data presentations, graphical presentations and interpretive statements on an advisory basis. These are presented for review and interpretation by the clinician. **Spirometry** - **Intended Use** Using the optional spirometry module and associated accessories to acquire, view, store and print measures and waveforms of pulmonary function. The spirometer should only be used with patients able to understand the instructions for performing the test. **Ambulatory Blood Pressure** - **Intended**		

	Use Using the optional ABP module and associated accessories the user can acquire, retrieve, view, store and print patient ambulatory blood pressure history.		

The Vitalograph Model 7000 Spirotrac underwent validation testing to ensure performance according to its specifications against current standards. These tests included performance testing against international standards such as

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

Validation of the interfaces with compatible third party devices is to ensure the integrity of the information is maintained and that the information on the third party devices 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:
The characteristics of the Model 7000 Spirotrac are similar to those of the predicate devices listed.

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