October 14, 2020

Vitalograph Ireland Ltd.
% Paul Dryden
Consultant
ProMedic, LLC
131 Bay Point Dr. NE
St. Petersburg, Florida 33704

Re: K201562
Trade/Device Name: Vitalograph Spirotrac Model 7000
Regulation Number: 21 CFR 868.1840
Regulation Name: Diagnostic Spirometer
Regulatory Class: Class II
Product Code: BZG
Dated: September 10, 2020
Received: September 11, 2020

Dear Paul Dryden:

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,

for Malvina B. Eydelman, M.D.
Director
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement on last page.

510(k) Number *(if known)*

K201562

Device Name

Vitalograph Spirotrac Model 7000

Indications for Use *(Describe)*

The Vitalograph Spirotrac Model 7000 is a PC-based software application 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 product is designed for use on adults and pediatrics, 5 years and older, in a variety of professional healthcare environments, e.g. primary care, hospitals and occupational health centers 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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510(k) Summary

Date Prepared: 13-Oct-2020

I Submitter

Vitalograph Ireland Ltd.
Gort Road Business Park
Ennis Co Clare V95 HFT4 Ireland
Tel - +353-65-6864100

Submitter Contact: Tony O'Hanlon
Regulatory Affairs / Quality Assurance Manager

Submission Correspondent: Paul Dryden
ProMedic, LLC

II Device

Proprietary or Trade Name:	Vitalograph Spirotrac Model 7000
Common/Usual Name:	Diagnostic spirometer
Classification Name:	Diagnostic spirometer (21 CFR 868.1840)
Regulatory Class:	II
Product Code:	BZG

III Predicate Device: Vitalograph Model 7000, K141546

IV Device Description:

The Vitalograph Spirotrac Model 7000 provides 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 integrates and reads / displays information from compatible Pulse Oximetry devices, Blood Pressure and Weight measurements devices, and ECG test devices.

Its primary functions are:

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 its 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).

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.

Navigation is allowed via the use of a standard PC keyboard and mouse or touchscreen.

V Indications for Use:

The Vitalograph Spirotrac Model 7000 is a PC-based software application 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 product is designed for use on adults and pediatrics, 5 years and older, in a variety of professional healthcare environments, e.g. primary care, hospitals and occupational health centers under the supervision of a healthcare provider.

Environments of use: Professional healthcare environments, e.g. primary care, hospitals and occupational health centers.

VI Modifications

A new code base, rewrite of the application, use of interfacing with latest Windows technology, User Interface etc. There were no changes to the algorithm.

Mechanical:
None, this is a software only device

Electrical:
None, this is a software only device

Materials:
None, this is a software only device

Software:
A new code base, rewrite of the application, use of interfacing with latest Windows technology, User Interface etc.

VII Comparison of Technological Characteristics and Performance with the Predicate

Table 1 is a comparison – Subject Device vs. the Predicate, K141546 including technological characteristics and performance.

Table 1: Comparison of the **Model 7000 Spirotrac** vs. the Predicate

	Predicate **Model 7000 Spirotrac**	**Subject** **Vitalograph Spirotrac Model 7000**	**Comparison**
K#	**K141546**	**K201562**	**-**
Product Code	**BZG**	**BZG**	**Same**
CFR	868.1840	868.1840	**Same**
Classification	Spirometer, diagnostic	Spirometer, diagnostic	**Same**
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.	The Vitalograph Spirotrac Model 7000 is a PC-based software application 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 product is designed for use on adults and pediatrics, 5 years and older, in a variety of professional healthcare environments, e.g. primary care, hospitals and occupational health centers under the supervision of a healthcare provider.	**The indications for use have been updated from the predicate K141546 which was not specific regarding the type of testing performed, patient population or environments of use. Otherwise the indications for use are the same.**
Fundamental scientific technology	Digital data communication	Digital data communication	**Same**
Spirometry - acquire, view, store and print measures and waveforms of pulmonary function	Yes	Yes	**Same**
ECG waveforms – view, store, print	Yes	Yes	**Same**
ECG waveforms - acquire	Yes, From compatible device.	Yes, From compatible device.	**Same**
ECG waveform- view, store, print	Yes	Yes	**Same**
ECG Interpretation via algorithms	Yes	Yes	**Same**
Ambulatory Blood Pressure - retrieve, view, store and print patient ambulatory blood pressure history	Yes, from compatible device.	Yes, from compatible device.	**Same**

	Predicate Model 7000 Spirotrac	Subject Vitalograph Spirotrac Model 7000	Comparison
K#	**K141546**	**K201562**	**-**
Spot Oximetry download, view.	Yes, From compatible device.	Yes, From compatible device.	**Same**
Weight	Manual entry or download via connection to compatible device	Manual entry or download via connection to compatible device	**Same**
Microsoft windows Operating Systems Supported:	Yes, Windows 7 and 8	Yes, Windows 7, 8 and 10	**Support for newer operating system**
Database:	MS SQL Server	MS SQL Server	**Same**
Where used	Hospital, Health center, primary care practices and clinics	Hospital, Health center, primary care practices and clinics	**Same**
Networked operation	Yes	Yes	**Same**
Subject Management: Demographic Entry, Maintenance and Deletion	Yes	Yes	**Same**
Report Printing	Yes	Yes	**Same**
Spirometry testing	Yes	Yes	**Same**
Trending Graphs for Spirometry Results	Yes	Yes	**Same**
Spirometry Predicted Value Equations	Yes	Yes	**Same**
Population Group Management	Yes	Yes	**Same**
Data Import/Export	Yes	Yes	**Same**
Subject and Spirometry Data Export	Yes	Yes	**Same**
Manual data entry of results	Yes	Yes	**Same**
Data export via Email	Yes	Yes	**Same**
Database Management	Yes	Yes	**Same**
Color Display	Yes	Yes	**Same**
Population groups	Adult, Pediatric	Adult, Pediatric (5 years and above)	**Same**
Communication	Bluetooth, USB,	Bluetooth, USB,	**Same**
Storage	Dependent on storage media	Dependent on storage media	**Same**
Biocompatibility	No patient contact	No patient contact	**Same**

VIII Performance Data

Non-clinical Testing

Performance testing demonstrated that the subject device met its acceptance criteria. Testing included:

Software
Verification and Validation was performed following Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 2005 and General Principles of Software Validation Guidance. January 2020.

Bench

- ATS / ERS (2005) waveform simulator testing
- ISO 23747:2015- Anaesthetic and respiratory equipment — Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans
- ISO 26782:2009 - Anaesthetic and respiratory equipment — Spirometers intended for the measurement of time forced expired volumes in humans.

Note that this testing was performed to demonstrate that the data displayed along with any limits set by user or by default, are aligned with these performance standards.

There is no hardware so electrical safety, electromagnetic compatibility, biocompatibility, and cleaning testing were not required.

Substantial Equivalence Conclusion
The performance testing has demonstrated that the subject devise met the applicable standard performance requirements. The sponsor has demonstrated through performance testing, design and features, and non-clinical testing that the proposed device and predicate are substantially equivalent.