January 26, 2022

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

Re: K212938
Trade/Device Name: Vitalograph Model 6000 Alpha
Regulation Number: 21 CFR 868.1840
Regulation Name: Diagnostic Spirometer
Regulatory Class: Class II
Product Code: BZG
Dated: December 21, 2021
Received: December 22, 2021

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,

Rachana Visaria, Ph.D.
Assistant Director
DHT1C: Division of Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K212938

Device Name

Vitalograph Model 6000 Alpha

Indications for Use *(Describe)*

The intended use of the Vitalograph Model 6000 Alpha is the simple assessment of respiratory function through the measurement of dynamic lung volumes i.e. spirometry. The device measures patient respiratory parameters including FVC, FEV1, FEV6, PEF, MVV and VC. The device is designed to be operated by medical professionals trained in respiratory and lung function testing on adults and pediatrics, 5 years and older, in a variety of professional healthcare environments, e.g. primary care, hospitals and occupational health centers.

Type of Use *(Select one or both, as applicable)*

XX 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: 25-January-2022

I. Submitter

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Regulatory Affairs / Quality Assurance Manager

Submission Correspondent: Paul Dryden ProMedic, LLC

II. Device

Proprietary or Trade Name: Vitalograph Model 6000 Alpha
Common/Usual Name: Diagnostic spirometer
Classification Name: Diagnostic spirometer (21 CFR 868.1840)
Regulatory Class: II
Product Code: BZG

III. Predicate Device: K200550 – Vitalograph Model 2120 In2itive eDiary

Proprietary or Trade Name: Vitalograph Model 2120 In2itive eDiary
Common/Usual Name: Diagnostic spirometer
Classification Name: Diagnostic spirometer (21 CFR 868.1840)
Regulatory Class: II
Product Code: BZG

IV. Device Description:

The Vitalograph Alpha Model 6000 is a desktop spirometer which measures the following lung function parameters FVC, FEV1, FEV6, PEF, MVV and VC in professional healthcare environments, e.g., primary care, hospitals and occupational health centers.

It is externally powered from a Class II, IEC 60601-1 compliant medical power supply. It contains a rechargeable battery powered from the external supply. The device also contains an integral 4 inch thermal printer.

The device has a USB port for connection to other devices and an SD card slot for backup of stored data. The device also has wired ethernet and Wi-Fi for connection to a hospital network.

Its primary functions and technology are:

- Spirometry measurements using single breath and multiple-breath testing techniques, the display and recording of measured lung volumes and flow rates (including FVC, FEV1, FEV6, PEF, MVV and VC) are identical to the predicate device
- Record subject data
- Storage of data and test results on unit for later printing or export to Spirotrac software which was cleared under 510(k) K201562
- The Flowhead utilizes a Fleisch Pneumotachograph. The operating principle is identical to the predicate K200550
- User Interface navigation via touch screen display

V. Indications for Use:

The intended use of the Vitalograph Model 6000 Alpha is the simple assessment of respiratory function through the measurement of dynamic lung volumes i.e. spirometry. The device measures patient respiratory parameters including FVC, FEV1, FEV6, PEF, MVV and VC. The device is designed to be operated by medical professionals trained in respiratory and lung function testing on adults and pediatrics, 5 years and older, in a variety of professional healthcare environments, e.g. primary care, hospitals and occupational health centers.

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

VI. Comparison of Technological Characteristics and Performance with the Predicate

Table 1 is a comparison – Subject Device vs. the Predicate, K200550.

Table 1 - Comparison of Subject and Predicate Devices

	Predicate Model 2120 In2itive eDiary	Subject Device Model 6000 Alpha	Comparison
K#	**K200550**	**K212938**	**-**
Product Code	BZG	BZG	**Identical**
CFR	868.1840	868.1840	**Identical**
Classification	Spirometer, diagnostic	Spirometer, diagnostic	**Identical**
Indications for Use	The Vitalograph Model 2120 In2itive eDiary device is a battery-operated spirometer which measures three basic patient respiratory parameters (FVC, MVV and VC). The Vitalograph Model 2120 In2itive eDiary is a handheld spirometer designed for lung function testing in a variety of environments such as hospital wards, health centers and private homes. The Vitalograph Model 2120 In2itive eDiary can be configured as a stand-alone spirometer or connected to a printer.	The intended use of the Vitalograph Model 6000 Alpha is the simple assessment of respiratory function through the measurement of dynamic lung volumes i.e. spirometry. The device measures patient respiratory parameters including FVC, FEV1, FEV6, PEF, MVV and VC. The device is designed to be operated by medical professionals trained in respiratory and lung function testing on adults and pediatrics, 5 years and older, in a variety of professional healthcare environments, e.g. primary care, hospitals and occupational health centers.	**Equivalent**
Fundamental scientific technology	Fleisch Pneumotachograph type Flowhead is connected to a transducer, with related signal-processing circuitry.	Fleisch Pneumotachograph type Flowhead is connected to a transducer, with related signal-processing circuitry.	**Similar**
Parameters measured	FVC, FEV1, FEV6, PEF, MVV and VC	FVC, FEV1, FEV6, PEF, MVV and VC	**Identical parameters**
Hand-held	Yes	Not a desktop	Same functionality in a different form
Patient Interface	Flowhead cone	Flowhead cone	**Similar**
Cleaning	Unit surface cleaning and 70% alcohol	Unit surface cleaning and 70% alcohol	**Similar**
Patient use	Unit surface cleaning and 70% alcohol	Unit surface cleaning and 70% alcohol	**Similar**

Specifications	Predicate Model 2120 In2itive eDiary	Subject Device Model 6000 Alpha	Comparison
Back pressure	Less than 0.1kPa/L/second @ 14L/s	Less than 0.1kPa/L/second @ 14L/s	**Similar**
Volume detection	Flow integration sampling @ 100Hz	Flow integration sampling @ 100Hz	**Similar**
Maximum displayed volume	10L	10L	**Similar**
Volume accuracy	±3% or 0.05L (±2.5% for device and ±0.5% for syringe)	±2.5%	**Similar**
Flow Accuracy when operated in operating temperature range conditions	Flow ±10% or 0.3 L/s Max. flow rate ±16 L/s Min. flow rate ±0.02 L/s	Flow Accuracy ±10% Max. flow rate ±16 L/s Min. flow rate ±0.02 L/s	**Similar**
Operating temperature range	10–40ºC	10–40ºC	**Similar**
Performance standards	ATS/ERS (2005) ISO 23747 ISO 26782	ATS/ERS (2019) ISO 23747 ISO 26782	**Similar,** the subject device complies with the latest version of ATS/ERS
Electrical Safety and EMC	ES 60601-1 IEC 60601-1-2 IEC 60601-1-11	ES 60601-1 IEC 60601-1-2	**Similar** but subject device is not intended for home use
Communications	USB	USB, Ethernet, WiFi	**Similar** , additional connectivity in subject device
Device weight	0.230 kg	1.5 kg	Not critical too equivalence
Dimensions	160 x 100 x 45mm	204mm (length) x 253mm (width)	Not critical too equivalence
Interface	Touchscreen LCD	Color touchscreen	**Similar**
Power / Energy Source	5V/3.7V Li-ion rechargeable battery	7.2V, 2.2Ahr NiMH	**Similar**
Biocompatibility	Surface Contact, Skin / Mucosa, Limited Duration	Externally Communicating, Tissue and Surface Contact, Skin / Mucosa, Limited Duration	**Similar**

VII. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility –
The patient contacting materials were evaluated using: ISO 10993-5(2009) – Cytotoxicity, ISO 10993-10 (2010) – Sensitization and Irritation, ISO 10993-18 (2020) – Chemical Characterization, ISO 18562-2 (2017) – Particulate Materials, ISO 18562-3(2017) – VOC, with a toxicological risk assessment. The material were found to be acceptable for their intended use.

Electrical Safety and EMC
Electrical safety and EMC testing were conducted on the subject device. The system complies with AAMI ANSI ES 60601-1: 2005 + A1: 2012 and IEC 60601-1-2:2014 for EMC.

Software Verification and Validation Testing
Software verification and validation testing were conducted. The software for this device was considered as a "moderate" level of concern.

Mechanical, Animal, and Clinical Testing
Cleaning validation, aging. There was no animal or clinical testing was performed.

Bench Testing
Performance testing per ATS/ERS (2019) for peak flow and timed forced expired volume per ISO 23747:2015- Peak Flow and ISO 26782:2009 – Timed Forced Expired Volume was performed.

IX. Conclusion

Discussion of Differences –
The identified differences do not raise new or different concerns of safety or effectiveness relative to the predicate.

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