July 27, 2020

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

Re: K200550
Trade/Device Name: Vitalograph Model 2120 In2itive eDiary
Regulation Number: 21 CFR 868.1840
Regulation Name: Diagnostic Spirometer
Regulatory Class: Class II
Product Code: BZG
Dated: June 27, 2020
Received: June 30, 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 Michael Ryan
Director
DHT1C: Division of ENT, 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: 06/30/2020
See PRA Statement on last page.

510(k) Number *(if known)*

K200550

Device Name

Vitalograph Model 2120 In2itive eDiary

Indications for Use *(Describe)*

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 centres and private homes. It is intended for Adults and pediatrics, 5 years and older.

The Vitalograph Model 2120 In2itive eDiary can be configured as a stand-alone spirometer or connected to a printer.

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.

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

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Date Prepared: 27-July-2020

I. Submitter

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

Submission Correspondent: Paul Dryden ProMedic, LLC

II. Device

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

III. Predicate Device: K100687 – Vitalograph Model 2120

IV. Device Description:

The Vitalograph Model 2120 In2itive eDiary is a hand-held, battery-operated spirometer which measures the following lung function parameters FVC, MVV and VC in hospital, clinical and home settings.

It can be configured as a standalone spirometer or connected to a printer.
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, VC, MVV) and other parameters which are subsets of these measured parameters.
- Record subject data. Storage of data and test results on unit for later printing or export to Spirotrac software
- The Flowhead utilizes a Fleisch Pneumotachograph.
- User Interface navigation via five buttons (Up, Down, Enter/Select, Cancel/Esc and Power On/Off) or an optional touch screen.

V. 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 centres and private homes. It is intended for Adults and pediatrics, 5 years and older.

The Vitalograph Model 2120 In2itive eDiary can be configured as a stand-alone spirometer or connected to a printer.

Environments of use: Hospital wards, health centres and private homes

VI. Modifications

The subject device includes modifications to the predicate. These modifications include:

Mechanical:

- New display and touch panel
    - There is a new display which required that the outer housing be revised to accommodate the larger display and touch panel.

Electrical:

- Change of user interface to a 4.3" color LCD with capacitive touch panel (was 2.8" resistive)
- Inclusion of codec for sound generation, but the unmodified Model 2120 also provided sound
- Update to support Linux Operating System

Materials:

- Flowhead outer housing material has changed
    - These are patient contacting materials which have been tested via ISO 10993-1

Software:

- Support for user interface above
- Use of an embedded Linux Operating System
- Support for Codec as above

VII. Comparison of Technological Characteristics and Performance with the Predicate

Table 1 is a comparison – Subject Device vs. the Predicate, K100687 including technological characteristics and performance.

Table 1: Comparison of the Model 2120 In2itive eDiary vs. the Predicate

	Predicate Model 2120	Subject Device Vitalograph Model 2120 In2itive eDiary	Comparison
K#	**K100687**	**K200550**	**-**
Product Code	**BZG**	**BZG**	**Same**
CFR	868.1840	868.1840	**Same**
Classification	Spirometer, diagnostic	Spirometer, diagnostic	**Same**
Indications for Use	The device is a battery-operated spirometer which measures three basic patient respiratory parameters (FVC, MVV and VC). The Model 2120 is a handheld spirometer designed for lung function testing in a variety of environments such as hospital wards, health centres and private homes. The Model 2120 can be configured as a stand-alone spirometer or connected to a printer.	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 centres and private homes. It is intended for Adults and pediatrics, 5 years and older. The Vitalograph Model 2120 In2itive eDiary can be configured as a stand-alone spirometer or connected to a printer.	The indications for use for the Model 2120 In2itive eDiary are identical to the predicate Model 2120 with just the device name updated.
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.	Same
Parameters measured	FVC, MVV and VC	FVC, MVV and VC	Same
Hand-held	Yes	Yes	Same
Patient Interface	Flowhead cone	Flowhead cone	Same
Cleaning	Unit surface cleaning and 70% alcohol	Unit surface cleaning and 70% alcohol	Same
Patient use	Single Patient, multi-use	Unit surface cleaning and 70% alcohol	Same
Specifications			
Back pressure	Less than 0.1kPa/L/second @ 14L/s	Less than 0.1kPa/L/second @ 14L/s	Identical
Volume detection	Flow integration sampling @ 100Hz	Flow integration sampling @ 100Hz	Identical
Maximum displayed volume	10L	10L	Identical
Volume accuracy ±3% or 0.05L	Yes	Yes	Identical

	Predicate Model 2120	**Subject Device Vitalograph Model 2120 In2itive eDiary**	**Comparison**
Min. Volume	0.01L	0.01L	Identical
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 ±10% or 0.3 L/s Max. flow rate ±16 L/s Min. flow rate ±0.02 L/s	Identical
Linearity	Better than ±3%	Better than ±3%	Identical
Operating temperature range	10–40ºC	10–40ºC	Identical
Performance standards	ATS/ERS (2005) ISO 23747 ISO 26782	ATS/ERS (2005) ISO 23747 ISO 26782	Identical
Electrical Safety and EMC	ES 60601-1 IEC 60601-1-2	ES 60601-1 IEC 60601-1-2 IEC 60601-1-11	Similar. Added IEC 60601-1-11 for home use which had not been done for the predicate
Storage Temperature	0–50°C	0–50°C	Identical
Storage Relative Humidity	10%–95%	10%–95%	Identical
Communications	USB x 1 for connection to Spirotrac	USB x 1 for connection to Spirotrac	Identical
Device weight	0.310Kg	0.230Kg	Similar
Dimensions	186 x 110 x 48 mm	160 x 100 x 45mm	Similar
Interface	Touchscreen LCD	Touchscreen LCD Buttons, buttons were not used in practice	No. Differences do not raise new concerns
Power / Energy Source	5V/3.7V Li-ion rechargeable battery	5V/3.7V Li-ion rechargeable battery	Identical
Biocompatibility	Surface Contact, Skin / Mucosa Limited Duration	Surface Contact, Skin / Mucosa Limited Duration	Identical patient contact New material tested to ISO 10993-1

VII. Performance Data

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

Biocompatibility –
The patient contacting materials were identical to the predicate and review of the geometry and processing did not raise new or different concerns. For those that were different they were considered Surface Contact, Intact skin or Mucosa contacting with limited duration of contact and tested to ISO 10993-5 – Cytotoxicity and ISO 10993-10 – Sensitization and Irritation and found to be non-cytotoxic, non-irritating and non-sensitizing.

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 and IEC 60601-1-11:2015 for home use.

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
No mechanical, animal or clinical testing was performed.

Bench Testing
Performance testing per ATS/ERS 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. Conclusions

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. The sponsor has demonstrated through performance testing, design and features, and non-clinical testing that the proposed device and predicate have been found to substantially equivalent.