DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 26, 2016

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

Re: K160253
Trade/Device Name: Vitalograph Model 6300 micro
Regulation Number: 21 CFR 868.1840
Regulation Name: Diagnostic spirometer
Regulatory Class: II
Product Code: BZG
Dated: July 25, 2016
Received: July 27, 2016

Dear Mr. Tom J. 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

Tina Kiang, Ph.D.
Acting 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)*
K160253

Device Name
Vitalograph Model 6300 micro

Indications for Use *(Describe)*
The device is a spirometer which measures patient respiratory parameters including FVC, FEV1, FEV6, PEF, MVV and VC. The Vitalograph micro is a handheld 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:
   Contact Person / Official Correspondent: Mr. Tom J Healy
   Regulatory Affairs / Quality Assurance Manager

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

   Tel: +353656864100
   Fax: +353656829289.

   Date prepared: 15th January 2016.

2. Common / Usual name (s):

   Vitalograph Model 6300 micro

   Panel: Anesthesiology
   Class 2 Diagnostic Spirometer as classified per 21 CFR 868.1840.
   Product Code BZG.

3. Predicate Device:

   Manufacturer : Vitalograph
   Device Name : Model 2120
   510(k) No : K100687, Class 2, Product Code BZG.
   Classified per 21 CFR 868.1840

   Manufacturer : Vitalograph
   Device Name : Model 6800 Pneumotrac
   510(k) No : K142812, Class 2, Product Code BZG.
   Classified per 21 CFR 868.1840

4. Description of Device:

   Vitalograph Model 6300 micro is a handheld portable spirometer for performing Spirometry testing to aid in measuring the effect of lung disease on pulmonary function. The device may be used in hospital, healthcare facilities and homes under the supervision of a healthcare provider.

   The intended use of the 6300 micro is in the simple assessment of respiratory function through the measurement of dynamic lung volumes i.e. spirometry.

   The proposed device consists of a main body which incorporates an LCD, a touch panel, pressure transducer and flow circuitry as well as a detachable flow head. The device is used with a pulmonary function filter. Reports may be printed using the USB cable provided.

Principles of Operation: The Vitalograph micro measures a subject's lung ventilation by using a flowhead containing a Fleisch Pneumotachograph capable of giving linear signals throughout the entire physiological range. During testing, the airflow through the flowhead produces a pressure differential. Internally this pressure is applied to a pressure transducer, which produces an electric signal. This signal is converted into digital form so that the unit can perform calculations and display the results.

Primary functions are:

- Interaction will be via the touch screen interface.
- The model 6300 Compact performs spirometric measurements using the established fleisch Pneumotachograph, using single breath and multiple-breath testing techniques, to display and record lung volumes and flow rates (including FVC, FEV1, FEV6, PEF, MVV and VC) and their sub-divisions to aid in the measuring the effect of lung disease on pulmonary function
- Record subject demographic data.
- Produce printed reports to external printers.

5. Indications for Use:

The device is a spirometer which measures patient respiratory parameters including FVC, FEV1, FEV6, PEF, MVV and VC. The Vitalograph micro is a handheld 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.

6. Technological Characteristics

Differences:
The differences between the Model 6300 device and the predicate Model 2120, K100687 revolve around the Model 6300 has a touchscreen for navigation only while the predicate device Model 2120 is used with touchscreen or button navigation. The profile and weight of the devices are also similar as outlined below where the model 6300 is lighter and dimensionally smaller. The model 6300 employs a colour display and has USB and Bluetooth options where the model 2120 allowed USB and SD card. For power the model 6300 uses USB power or replaceable batteries where the predicates, model 2120 is rechargeable and the model 6800 uses USB power only.

Similarities:
The proposed device uses scientific concepts, operating principles and materials already cleared in the predicate devices submissions. As such the differences outlined are not critical to the intended therapeutic, diagnostic, prosthetic, or surgical use of the device, and do not affect the safety and effectiveness of the device when used as labelled.

For performance, the same flow measurement and operating principles are used on the predicate devices and the Vitalograph Model 6300 device.

The flow circuit in the model 6300 is identical to the circuit and transducer as the Vitalograph Model 2120 {ref K100687} and has the same touchscreen input mechanism, interface and functionality as cleared model 2120.

The indications for use for the Vitalograph 6300 micro now include pediatric population in line with the updated FDA guidance. The Model 6300 has the same indications for use, including pediatric population, as the Model 6800 as cleared under K142812. No new testing was required for this revised indication for use. The proposed device complies with the existing international performance standards to cater for all population groups. The micro device includes new parameters in the indications for use.

Materials used have been previously cleared in the predicate. No new biocompatibility testing was required to use these materials.

In relation to Patient interface accessories the Model 6300 will use the previously cleared Model 2820 mouthpieces and Nose clips which have their active device listings.

The characteristics of the Model 6300 are similar to those of the predicate devices listed in comparison table below. The similarities are

- Non-sterile device, components and accessories.
- Touchscreen user interface,
- Same indications for use
- Same operating principle and flow measurement principles.
- Same parameters calculation.
- Same method of use.
- Same performance when bench tested against performance standards.
- Same patient interface accessories.
- Same cleaning method.

Risks have been evaluated and the performance has been validated. This validation is on file for all devices.

Clinical testing was not carried out on the 6300 micro. The Vitalograph Model 6300 underwent non-clinical 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}.

Mechanical shock testing was also performed to evaluate the effects on the device during transport.

These tests included:

- Drop test of the packaged device from a specified height onto all corners and edges.
- Storage conditions testing.
- Operating temperature limits testing.
- Cleaning method validation was completed.

All tests and validations demonstrated satisfactory results. The Model 6300 Micro successfully passed the performance requirements of these tests and compliance to the requirements of the standards was achieved.

As such, the model 6300 performance is substantially equivalent to the legally marketed predicate devices.

Evidence of successful completion of tests and validations has been provided with this submission.

	Micro 6300	**K100687 Model 2120 {predicate}**	**Vitalograph model 6800 Pneumotrac K142812.**
Spirometry - acquire, view, store and print measurements and waveforms of pulmonary function	Yes	Yes	Yes
Environment of Care	Hospital wards, health centres and homes	Hospital wards, health centres and homes	Hospital wards, health centres and homes
Volume Range:	0-10 Litres	0-10Litres	0-10 Litres
Report Printing (via Vitalograph Reports)	Yes	Yes	Yes, via Spirotrac {K141546}
Spirometry testing	Yes	Yes	Yes
Colour Display	Yes	Yes	Yes, via Spirotrac {K141546}
Interface	Touchpanel (plus On/Off button)	Touchpanel & Buttons	On/Off switch. Power button. Navigation via Spirotrac (K141546)

Target Population	Adult & Pediatric (5yrs and over)	Adult, Pediatric	Adult & Pediatric (5yrs and over)
Communication	USB, Bluetooth	USB, Micro SD card	USB
Storage	Non-volatile data storage	Non-volatile data storage	via Spirotrac {K141546}
Sterile device or components	No	No	No
Regulatory (USA):	FDA - 510(k) Class 2	FDA - 510(k) Class 2 K100687	FDA - 510(k) Class 2 K142812
Device weight	0.250Kg	0.230Kg	0.450Kg
Dimensions	83 x 91x 32 mm	160x100x45mm	183x105x70mm
Power	5V USB /6V AAA Alkaline Batteries	3V AAA Alkaline Batteries	5V USB
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}	10 to 40oC {At least 17-37oC required per ATS 2005}
Storage Temp:	0 - 50 °C	0 - 50 °C	0 - 50 °C
Humidity:	10 - 95% relative humidity	10 - 95% relative humidity	10 - 95% relative humidity
Non-Clinical Testing to Performance Standards {incl bench tests}:	ATS ERS 2005, ISO 23747:2009 for PEF. EN ISO 26782:2009 IEC / EN 60601 {EN 60601-1-1 and EN 60601-1-2} Drop tests. Storage conditions. Operating temperature Cleaning validation	ATS ERS 2005, ISO 23747:2009 for PEF. EN ISO 26782:2009 IEC / EN 60601 {EN 60601-1-1 and EN 60601-1-2} Drop tests. Storage conditions. Operating temperature	ATS ERS 2005, ISO 23747:2009 for PEF. EN ISO 26782:2009 IEC / EN 60601 {EN 60601-1-1 and EN 60601-1-2} Drop tests. Storage conditions. Operating temperature. Cleaning validation
Device materials	ABS plastic Body, Silicone Rubber, Stainless Steel, Aluminium,	ABS plastic Body, Silicone Rubber, Stainless Steel, Aluminium,	ABS plastic Body, Silicone Rubber, Stainless Steel, Aluminium, TPX plastic
Biocompatibility	No new testing required. All materials previously cleared in K100687 (same duration of exposure and usage)	No new testing required. No new testing required. All materials previously cleared in K073155 (same duration of exposure and usage)	No new testing required. All materials previously cleared in K100687 & K925085.
Patient interface accessories	Model 2820 BVF Mouthpiece, Single; patient use.	Model 2820 BVF Mouthpiece, Single; patient use.	Model 2820 BVF Mouthpiece (K942779) {Class 2

	510(k) K942779. Product Code BZG Vitalograph Nose Clip, Single; patient use {Class 1, 510(k) exempt, with an active device listing. Device listing D130170. Product Code BXJ. Previously cleared in K100687,	510(k) K942779. Product Code BZG Model 2020 SafeTway Mouthpiece. Single; patient use {Class 1, 510(k) exempt, with an active device listing. Device listing: D141382. Product Code BYP, Vitalograph Nose Clip, Single; patient use {Class 1, 510(k) exempt, with an active device listing. Device listing D130170. Product Code BXJ	with an active device listing}.
Patient interface accessories contacting the gas pathway	Model 2820 BVF Mouthpiece, Single; patient use. 510(k) K942779. Product Code BZG	Model 2820 BVF Mouthpiece, Single; patient use. 510(k) K942779. Product Code BZG	Model 2820 BVF Mouthpiece, Single; patient use. 510(k) K942779. Product Code BZG
FDA Product Code, Device Class, 21 CFR section	BZG, Class 2, 868.1840	BZG, Class 2, 868.1840	BZG, Class 2, 868.1840
Indications for Use	The device is a spirometer which measures patient respiratory parameters including FVC, FEV1, FEV6, PEF, MVV and VC. The Vitalograph micro is a handheld 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 device is a battery operated spirometer which measures patient respiratory parameters. The model 2120 is a hand held 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	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

	the supervision of a healthcare provider.	connected to a printer.	private homes under the supervision of a healthcare provider.

11. Conclusion:

The characteristics of the Model 6300 Micro 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 substantially equivalent to the predicate devices.

No new issues of safety or effectiveness have been introduced as a result.