510K Summary

as required by 21 CFR 807.92

K100687

OCT 16 2010

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

   Tel: +353656864100
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2. Contact Person / Official Correspondent:
   Mr. Tom J Healy
   Regulatory Affairs / Quality Assurance Manager

3. Date of Submission:
   January 25th 2010.

4. Device Trade Name:
   Vitalograph Model 2120

5. Common / Usual name:
   Hand Held Spirometer,

6. Classification number:
   Spirometer as classified in Class II per 21 CFR 868.1840

   Extracted from 21 CFR 868 on September 28, 2007:

Subpart B--Diagnostic Devices

Sec. 868.1840 Diagnostic spirometer.

(a) *Identification.* A diagnostic spirometer is a device used in pulmonary function testing to measure the volume of gas moving in or out of a patient's lungs.

(b) *Classification.* Class II (performance standards).

7. Predicate Device:

Manufacturer	: Vitalograph
Device Name	: 2120 Hand Held Spirometer
510(k) No	: K946075
Manufacturer	: Cardinal Health
Device Name	: SpiroPro
510(k) No	: K092324

8. Description of Device:

The Vitalograph Model 2120 is intended to be used, as its predecessor, as a battery operated spirometer which measures three basic patient respiratory parameters {FVC,

MVV and VC}. 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 connected to a printer.

The Model 2120 series has been available to the marketplace for over 15 years {ref K946075}. This device is a hand held electronic Spirometer, used in the simple assessment of respiratory function through the measurement of dynamic lung volumes i.e. Spirometry. This revised design is an upgrade to the existing product in terms of modernising its look and feel {i.e. changes to ergonomics and user interface}. The intended uses and operating principles in relation to its measurement of respiratory function remain unchanged.

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 FVC, VC, MVV) and it's subdivisions,
2. Record subject data. Storage of data and test results on unit for later printing or export to Spirotrac {see K912412},
3. The flowhead will be a Fleisch Pneumotachograph type flowhead, the operating principle of which has been well established in the existing Model 2120 {K946075} and various other spirometers. {e.g. Vitalograph Compact Ref K854526, Vitalograph Alpha ref K873562, Vitalograph Escort K925085}

All variants of the Model 2120 {e.g. including In2itive, e-Diary} will use very same operating principle, LCD, Buttons, optional Touchscreen, and Mouldings. Items that may vary within the range are the list of parameters that the different variants display.

Navigation is allowed via the use of five buttons {Up, Down, Enter/Select, Cancel /Esc and power On/Off} or an optional touch screen.

9. Intended use:

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 connected to a printer.

10. Technological Characteristics

The Vitalograph Model 2120, as with its predecessor, the Vitalograph 2120, uses a Fleisch Pneumotachograph to measure lung function. These are intended to be handheld, portable devices. All are battery powered, with charging, and button operated.

The primary difference between the revised 2120 Hand Held Spirometer and the Vitalograph predicate device is the inclusion of an optional touch screen for navigating the simple icon driven menus along with the existing buttons and the inclusion of USB communication, where the predicate used serial communication, for data export / printing. An increase in memory in the proposed device to allow the storage of more tests and subjects {up to 1,000 tests and 10,000 subjects} is also in place. The memory continues to be of the same type as the predicate but allows for an increase in storage due to the larger capacities currently available.

Both proposed and predicate Vitalograph devices continue to use a Fleisch Pneumotachograph in their flowhead design, they both have simple button navigation options {Up, Down, Power On-Off, Del / Cancel} and they both are handheld, battery powered devices that have a charging cradle.

The use of Touchscreen interface, whilst newly incorporated into the Vitalograph proposed design, is currently available in the other predicate devices listed, as well as the pneumotach measuring principle.

There has been no change to the operating principle used by either the submitted device or its predicate. The flowhead will be a Fleisch Pneumotachograph type flowhead, the operating principle of which has been well established in the existing Model 2120 {K946075} and various other Vitalograph spirometers. {E.g. Vitalograph Compact Ref K854526, Vitalograph Alpha ref K873562, Vitalograph Escort K925085}.

Safety and effectiveness have been assured through the extensive testing in relation to IEC 60601 standards for electrical safety and EMC/EMI, as well as device specific performance testing to American Thoracic Society {ATS}and International Organisation for Standardisation {ISO} standards.

Table 1. Comparison with Predicate.

	Vitalograph Model 2120 Specifications	**Predicate Device – Vitalograph 2120 Specifications -** K946075	**Predicate Devices – KoKo Legend K051572**	**Predicate Devices – SpiroPro K092324 / K031515**
Volume Range:	0-10 Litres	0-8Litres		0.1 – 8 Litres
Max Flow Range	0-16 Litres / second	0-16 Litres / second	16 Litres / second	0.1-16 Litres / second
Back Pressure	Less than 0.1kPa/L/s	0.1kPa/L/s	1.5 cmH20/l/s	Maximum 2kPa at 15 L/s
Accuracy FEV1:	+/- 3%	+/- 3%	+/- 3%	+/- 3%
Accuracy FEV6	+/- 3%	+/- 3%	+/- 3%	+/- 3%
Accuracy PEF	+/-5%	+/-5%		+/- 5%
Calibration	Using calibration syringe	Using calibration syringe	Using calibration syringe	Using calibration syringe
Technology:	Fleisch Pneumotachograph	Fleisch Pneumotachograph	Pneumotach	Pneumotach

Set Predicted / reference values	Yes	Yes	Yes	Yes
Memory Type / Storage:	Yes, Non-volatile data storage	Yes, Non-volatile data storage	Not available	Yes, Non-volatile data storage
Sounds:	Audible beeps emitted during power on, whilst performing a test, at end of test and for each key press.	Audible beeps emitted during power on, whilst performing a test, at end of test and for each key press.	Not available	Not available
Communication:	USB, Micro SD card	Serial	RJ45, Serial	Serial , Bluetooth
Export of data to Spirotrac {K912412}	Yes	Yes	Not to Spirotrac, but does export to its own KoKoPFT windows PC software	Not to Spirotrac, but does export to its own SpiroPro windows PC software
To be serviced	Yes, Service Manuals.	Yes, via Service Manuals.	Not available	Not available
Connection to external printer	Yes	Yes	Yes	Yes
Battery Warnings:	On-screen Battery Low, and Battery Icon {Flashing icon}	Low Battery warning and audible beeps.	Yes	Not available
Battery Type {power}:	3v, 2 x 1.5v AAA	3v Li coin cell (CR2450)	12v DC	3.7v Li ion battery
Autopowerdown	2-10minutes	2 minutes	Not available	Not available
Dimensions:	160 x 100 x 45 mm	215 x 130x 70 mm	235 x 254 x 70mm	150 x 96 x 40mm
Weight:	Device Incl batteries 230g.	Device Incl batteries 520g.	1600g	200g including battery
Material Type:	PC/ABS, Silicone Rubber, Stainless Steel,	PC/ABS, TPX, Acetal, Polyester, Aluminium, Stainless Steel	Not available	Rotec ABS 1001FR V0
Operating Temp:	10-40°C. {At least 17-37°C required per ATS 2005}	5 to 40°C	10-40°C	Compliant with ATS
Storage Temp:	0 - 50 °C	0 - 50 °C	-20 to 70°C	Not available
Humidity:	10 - 95% relative humidity	10 - 95% relative humidity	10 - 90% relative humidity	Not available
Performance Standards:	ATS ERS 2005, ISO 23747:2007 for PEF {formerly EN13826:2003}. EN ISO 26782:2009	ATS & ERS {now combined into ATS / ERS 2005}	ATS / ERS 2005	ATS / ERS 2005
Compliance:	IEC / EN 60601 {EN 60601-1-1 and EN 60601-1-2}	IEC / EN 60601 {EN 60601-1-1 and EN 60601-1-2}	IEC / EN 60601 {EN 60601-1-1 and EN 60601-1-2}	Not available
Interface with user	Button keypad / Touchscreen	Button Keypad	Touchscreen	TouchScreen
Regulatory:	FDA - 510(k) CE {0086} Class 2a	FDA - 510(k) CE {0086} Class 2a	FDA 510K CE{0086}	FDA 510K CE {0123}
Warranty:	1 Year	1 Year	Not available	Not available

Conclusion:

The characteristics of the Model 2120 is similar to those of the Vitalograph predicate device listed in Table 1 above. The similarities are

- Same intended use
- Some operating principle
- Same spirometry parameters
- Same algorithm for spirometry parameters calculation.
- Same physical characteristics & method of use.

The characteristics of the Model 2120 is similar to those of the other predicate devices listed in Table 1 above. The similarities are

- Touchscreen interface with the user incorporated in proposed Model 2120 device is also incorporated into predicate devices.
- Proposed device is also a diagnostic spirometer in line with predicate devices.
- Pneumotach principle for measurement is employed in all predicate devices.
- Operating temperature, storage temperatures and relative humidity ranges are similar for proposed and predicate devices in line with ATS requirements.

Based on the above, including the successful completion of all device testing, Vitalograph conclude that this device is substantially equivalent to the legally marketed predicate devices and is safe and effective for use. No new risks have been introduced by the revised design.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Tom J. Healy
Regulatory Affairs/Quality Assurance Manager
Vitalograph (Ireland) Limited
Gort Road Business Park
Ennis, Co Clare, Ireland

OCT 16 2010

Re: K100687
Trade/Device Name: Vitalograph Model 2120-Hand Held Spirometer
Regulation Number: 21 CFR 868.1840
Regulation Name: Diagnostic Spirometer
Regulatory Class: II
Product Code: BZG
Dated: October 11, 2010
Received: October 14, 2010

Dear Mr. 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.

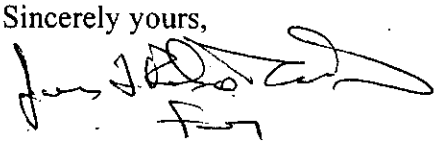
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,



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Director
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Enclosure

K100687

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Indications for Use

510(k) Number (if known): K100687

Device Name: Vitalograph Model 2120 – Hand Held Spirometer

Indications for Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K100687