

510K Summary

as required by 21 CFR 807.92

1. Company Information:

Name: Vitalograph (Ireland) Ltd

Address: Gort Road Business Park, Ennis, Co Clare, Ireland.

Tel: +353656864100

Fax: +353656829289.

2. Contact Person / Official Correspondent:

Mr. Tom J Healy

Regulatory Affairs / Quality Assurance Manager

3. Date of Submission:

8th February 2011.

4. Device Trade Name:

Vitalograph Model 7100

5. Common / Usual name:

Vitalograph Model 7100 VitaloJAK,

6. Classification number:

Recorder, magnetic tape, medical, Class II per 21 CFR 870.2800

7. Predicate Device:

Manufacturer : Karmelsonix

Device Name : Pulmotrack 5050 Wholter

{Recorder, magnetic tape, medical}

510(k) No : K101022

8. Intended Use / Description of Device:

The Model 7100 is a non-invasive battery operated device intended to acquire, record and store ambulatory cough sounds from patients for up to 24 hours. The device stores the data on a removable memory card for later playback, review, and analysis of the cough sounds on a windows based PC.

9. Technological Characteristics

The recording of respiratory sounds to a sound file over the two channels for up to 24 hours is achieved by:

- a) The contact sensor channel, which records the data for later analysis.
- b) An air microphone channel. This is used to monitor and to ascertain the validity of the data obtained in the channel described in (a.) above. This can be achieved by listening, or otherwise determining, signals such as speech and other noises that will be ignored when examining channel (a) data.

These two individual analogue signals are electronically conditioned and then digitally sampled. The sampled information data is then stored to a suitable internal memory module. The data will be transferred to the PC by removing the memory card from the VitaloJAK.

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.

The device itself is not diagnostic. It acquires the respiratory data for later review after removing the memory card and transferring the data to a PC. The user identifies each incident of coughing.

10. Comparison with Predicate

As with the predicate device the Vitalograph Model 7100 does not perform diagnosis.

As with the predicate device the Vitalograph Model 7100 underwent validation testing to ensure performance according to its specifications. All tests demonstrated satisfactory results. Evidence of successful validation has been provided with this submission.

	Vitalograph Model 7100	Karmelsonix Pulmotrack 5050 Wholter. {K101022}
Number of sensors	2 {incl ambient microphone}	4 {incl ambient sensor}
Acoustic sensors (attached to the patient using adhesive pads)	Yes	Yes
Non-invasive	Yes	Yes
Tension-sensitive respiration belt	No	Yes
Ambient microphone	Yes	Yes
Firmware and Flash memory	Yes	Yes
USB cable	No	Yes

11. Conclusion:

The characteristics of the Model 7100 is similar to those of the predicate device listed.

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 device and is safe and effective for use.



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

NOV 23 2011

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

Re: K110525
Trade/Device Names: Vitalograph Model 7100-- VitaloJAK
Regulatory Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II (Two)
Product Code: DSH
Dated: October 27, 2011
Received: November 3, 2011

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.

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,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110525

Device Name: Vitalograph Model 7100– VitaloJAK

Indications for Use:

The Model 7100 is a non-invasive battery operated device intended to acquire, record and store ambulatory cough sounds from patients for up to 24 hours. The device stores the data on a removable memory card for later playback, review, and analysis on a windows based PC.

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

M. G. Willehense

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K110525