MAY 3 0 2014

510(K) SUMMARY

510(K) Number K 133859

5.1 Applicant's Name:
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5.3 Date Prepared: December 19, 2013

5.4 Trade Name: Watch-PAT 200U ("WP200U")

5.5 Common or Usual Name: Ventilatory Effort Recorder

5.6 Classification Name: Breathing Frequency Monitor

5.7 Medical Specialty: Anesthesiology

5.8 Product Code: Ventilatory Effort Recorder, MNR

5.9 Device Class: Class II

5.10 Regulation Number: 868.2375

5.11 Panel: Anesthesiology

5.12 Predicate Devices:

- Watch-PAT200S-3 ("WP200S-3") (Itamar Ltd), cleared under K102567; product code MNR (ventilatory effort recorder)

5.13 Intended Use / Indication for Use:

The Watch-PAT200U (WP200U) device is a non-invasive home care device for use with patients suspected to have sleep related breathing disorders. The WP200U is a diagnostic aid for the detection of sleep related breathing disorders, sleep staging (Rapid Eye Movement (REM) Sleep, Light Sleep, Deep Sleep and Wake), snoring level and body position. The WP200U generates a peripheral arterial tonometry ("PAT") Respiratory Disturbance Index ("PRDI"), Apnea-Hypopnea index ("PAHI"), PAT sleep staging identification (PSTAGES) and optional snoring level and body position discrete states from an external integrated snoring and body position (SBP) sensor. The WP200U's PSTAGES and SBP provide supplemental information to its PRDI/PAHI. The WP200U's

PSTAGES and SBP are not intended to be used as the sole or primary basis for diagnosing any sleep related breathing disorder, prescribing treatment, or determining whether additional diagnostic assessment is warranted.

5.14 Device Description:

The Watch-PAT200U System (WP200U) is a non-invasive home care device for use with patients suspected to have sleep related breathing disorders. The WP200U is a diagnostic aid for the detection of sleep related breathing disorders [Respiratory disturbance index (RDI), apnea – hypopnea index (AHI)] and sleep staging (Rapid Eye Movement (REM), Light Sleep, Deep Sleep and Wake) based on Peripheral Arterial Tonometry (PAT), a non-invasive technology. According to the physician discretion, the WP200U may be connected to an external integrated snoring and body position (SBP) sensor.

The WP200U device consists of the following: (1) a unified PAT and pulse oximeter probe which is used to detect the PAT signal and to measure blood oxygen saturation; (2) an embedded actigraph, which is used to determine periods of sleep based on the motion of the wrist; (3) external integrated snoring and body position sensor – SBP (Optional); (4) electronics, which include a controller that records the signals provided by the PAT finger probe, oximeter, actigraph and SBP; (5) the device software; and (6) a power supply.

The Watch-PAT200U is identical to the already cleared Watch-PAT200S-3 except for Itamar Medical pulse oximetry which replaces the existing Nonin pulse oximeter.

5.15 Substantial Equivalence:

Intended Use

The intended use of the Watch-PAT200U is identical to the intended use of its predicate, the Watch-PAT200S-3 ("WP200S-3") (Itamar Ltd). The replacement of the Nonin pulse oximetry with Itamar Medical pulse oximetry does not alter the intended diagnostic use of the WP200U.

Comparison of Technological Characteristics

The WP200U, like its predicate the WP200S-3, is a ventilatory effort recorder that utilizes PAT technology.

The PAT probe was modified to include an oximeter feature by adding LED package to the probe including R and IR LEDs. Itamar's Pulse Oximeter, like the predicate Nonin pulse oximetry pulse oximeter, determines the arterial oxygen saturation from two wavelengths absorption spectrophotometry. The integration into the PAT sensor does not raise any new types of safety and effectiveness questions as oxygen content is being measured the same way.

The WP200U's zzzPAT software was modified, as compared to the WP200S-3 predicate software, to include a new algorithm to calculate oxygen saturation. This new algorithm was incorporated into the WP200U offline software (zzzPAT) because the predicate Nonin pulse oximetry which computed this data in its hardware is no longer part of the system. As similar data is being analyzed to produce the same output (oxygen saturation), this change does not raise new types of safety and efficacy questions.

Performance Testing
A series of safety and performance testing were performed to demonstrate that the WP200U does not raise any new issues of safety and efficacy. These tests include:

- Electrical safety and Electromagnetic compatibility testing per IEC 60601-1: 1988 + A1: 1991 + A2: 1995; EN 60601-1:1990+A1:1993+A2:1995+A13:1996 and IEC 60601-1:2005 + CORR.1 (2006) + CORR.2 (2007) / EN60601-1:2006 and IEC 60601-1-2:2007 CISPR 11:2009 A1:2010 - Part 1-2 and 60601-1-11:2010
- Software verification and validation
- Bench testing to show the addition of LEDs did not affect PAT signal measurement

All these tests demonstrate that the WP200U is substantially equivalent to its predicate without raising any new issues of safety or effectiveness.

Clinical Data
The accuracy of the pulse oximeter was assessed in a clinical study.
The purpose of the study was to evaluate the SpO2 accuracy and performance of the Itamar Medical Pulse Oximetry system (WP200U) during non-motion conditions over the range of 70-100% SaO2 to arterial blood samples assessed by CO-Oximetry for SpO2 validation.

The study was conducted in accordance to ISO 14155, following the pulse oximetry guidelines of ISO 80601-2 applicable sections, and Pulse Oximeters – Premarket Notifications Submissions [510(k)s] Guidance For Industry and Food and Drug Administration Staff (issued: March 4, 2013).

The study was performed in CLINIMARK Laboratories and included eleven healthy adult volunteer subjects.

The results of the study provide supporting evidence that the SpO2 accuracy performance of the Itamar Medical WP200U pass an A_{RMS} specification of ≤3 (A_{rms} 2.1) under steady state / nonmotion conditions for the range 70-100%.

Summary
Based on the performance testing results, including the electrical and electromagnetic testing, clinical study, software verification and validation process and bench tests, Itamar Ltd. believes that the WP200U System is substantially equivalent to its predicate.
A clinical study was conducted to validate the WP200U SpO2 accuracy vs. Reference CO-Oximetry.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

May 30, 2014

Itamar Medical LTD
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555 Thirteenth Street, NW
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Re: K133859

Trade/Device Name: Watch-PAT200U (WP200U)
Regulation Number: 21 CFR 868.2375
Regulation Name: Ventilatory Effort Recorder
Class: II
Product Code: MNR
Dated: May 2, 2014
Received: May 2, 2014

Dear Mr. Kahan:

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 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. 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.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
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Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K133859

Device Name: Watch-PAT200U (WP200U)

Indications for Use:

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Prescription Use __√____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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