JUN - 2 2011

510(K) SUMMARY

510(k) Number K102567

5.1 Applicant's Name:

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5.2 Contact Person:

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5.3 Date Prepared: June 2011

5.4 Trade Name: Watch-PAT 200S-3 ("WP200S-3")

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-2 ("WP200S-2") (Itamar Ltd), cleared under K081982; product code MNR (ventilatory effort recorder)
- Ultima Snoring Mike, model 0540 (Braebon Medical Corporation), cleared under K020312; product code MNR (ventilatory effort recorder).

- Embla Polysomnography system (PSG), cleared under K971813; product code GWQ (electroencephalograph).

5.12 Intended Use / Indication for Use:

The Watch-PAT200S-3 (WP200S-3) device is a non-invasive home care device for use with patients suspected to have sleep related breathing disorders. The WP200S-3 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 WP200S-3 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 WP200S-3's PSTAGES and SBP provide supplemental information to its PRDI/PAHI. The WP200S-3'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.

5.13 Device Description:

The Watch-PAT200S-3 System (WP200S-3) is a non-invasive home care device for use with patients suspected to have sleep related breathing disorders. The WP200S-3 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 WP200S-3 may be connected to an external integrated snoring and body position (SBP) sensor.

The WP200S-3 device is worn on the wrist and consists of the following: (1) a finger PAT probe, which is used to detect the PAT signal; (2) an embedded pulse oximeter using a second probe that is attached to another finger, for measuring blood oxygen saturation; (3) an embedded actigraph, which is used to determine periods of sleep based on the motion of the wrist; (4) external integrated snoring and body position sensor – SBP (Optional); (5) electronics, which include a controller that records the information supplied by the PAT finger probe, oximeter, actigraph and SBP; (6) the device software; and (7) a power supply.

The Watch-PAT200S-3 is identical to the already cleared Watch-PAT200S-2 with the addition of an optional snoring level and body position sensor and the required electronic and software modification. The integrated sensor (SBP) is an optional external hardware which can be connected to the WP200S-3 device and attached to the patient's chest right under the sternal notch for recording snoring and body position signals.

5.14 Substantial Equivalence:

Intended Use

The intended use of the WP200S-3 is substantial equivalence to the combination of the intended use of its predicates Watch-PAT200S-2 ("WP200S-2") (Itamar Ltd), Ultima Snoring Mike, model 0540 (Braebon Medical Corporation) and Embla Polysomnography system (PSG) and any minor differences do not alter the intended diagnostic value of the WP200S-3. The claim of measuring snoring level in decibels and body position, were supported by both software verification and validation activities and a clinical study.

Technological Characteristics and Mode of Operation

The WP200S-3, like its predicate the WP200S-2, is a ventilatory effort recorder that utilizes PAT technology.

The integrated snoring and body position sensor can be attached to the patient's chest right under the sternal notch for recording snoring intensity in decibels and body position signals.

The WP200S-3's software modification done to include the new algorithm which allows for further processing of the external integrated signals of snoring and body position raise no new issue of effectiveness, as demonstrated through software verification and validation and supportive clinical data.

The WP200S-3's principles of operation and technology are the same as the cleared WP200S-2's except for the operation and technology of the SBP sensor. This SBP sensor is similar in operation and technology to those of the WP200S-3 predicate devices.

Performance Testing

A series of safety and performance testing were performed to demonstrate that the WP200S-3 does not raise any new issues of safety and efficacy. These tests include:

- Electrical and electromagnetic testing
- Software verification and validation
- Clinical study

All these tests demonstrate that the WP200S-3 is substantially equivalent to its predicates without raising new issues of safety or effectiveness.

Summary

Based on the performance testing results, including software verification and validation process, Electrical and electromagnetic testing, clinical study, Itamar Ltd. believes that the WP200S-3 System is substantially equivalent to its predicates without raising new issues of safety or effectiveness.

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. Jonathan Kahn
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555 Thirteenth Street NW
Washington, District of Columbia 20004-1109

JUN - 2 2011

Re: K102567
Trade/Device Name: Watch-PAT 200S-3
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II
Product Code: MNR
Dated: May 13, 2011
Received: May 13, 2011

Dear Mr. Kahn:

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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K102567

Device Name: Watch-PAT200S-3 (WP200S-3)

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)

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

510(k) Number: K102567