510(k) Summary

MAY 2 3 2008

510(K) Number K080427

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5.3 Date Prepared: January 2008

5.4 Trade Name: Watch-PAT 100S-2 ("WP100S-2")

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-Pat100S ("WP100S") (Itamar Ltd), cleared under K042916; product code MNR (ventilatory effort recorder).
- BioSleep (Oxford BioSignal's Ltd.), cleared under K002622; product code GWQ (Electroencephalograph).
- Silent night II (Sleep Solutions Inc.) cleared under K981034; product code MNR (ventilatory effort recorder).
- Embla (Ferguson Medical) cleared under K971813, product code GWQ (electroencephalograph)

5.12 Intended Use / Indication for Use:

The Watch-PAT100S-2 (WP100S-2) device is a non-invasive home care device for use with patients suspected to have sleep related breathing disorders. The WP100S-2 is a diagnostic aid for the detection of sleep related breathing disorders and sleep staging (Rapid Eye Movement (REM) Sleep, Light Sleep, Deep Sleep and Wake). The WP100S-2 generates a peripheral arterial tonometry ("PAT") Respiratory Disturbance Index ("PRDI"), Apnea-Hypopnea index ("PAHI") and PAT sleep staging identification (PSTAGES). The WP100S-2's PSTAGES provides supplemental information to its PRDI/PAHI. The WP100S-2's PSTAGES is 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.

The WP100S-2 is not indicated for children less than 17 years old.

5.13 Device Description:

The WATCH-PAT100S-2 System (WP100S-2) is a non-invasive home care device for use with patients suspected to having sleep related breathing disorders. The WP100S-2 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) Sleep, Light Sleep, Deep Sleep and Wake) based on Peripheral Arterial Tonometry (PAT); a non-invasive technology.

The WP100S-2 device consists of: (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) Electronics, which include a controller that records the information supplied by the PAT finger probe, oximeter, and actigraph; (5) the device software; and (6) a power supply.

The device is worn on the wrist, and continuously measures the relative state of the vasomotor activity in the distal part of the finger, by a finger-mounted probe based on a plethysmographic method. The measured signal is acquired from a self contained, opto-pneumatic sensor.

5.14 Substantial Equivalence:

Intended Use
The intended use of the WP100S-2 is substantially equivalent to the combination of the intended use of its predicates and any minor differences do not alter the intended diagnostic value of the WP100S-2. The claim of sleep staging and breathing disorders indices, PRDI and its derivative PAHI, were supported by both software verification and validation activities and a clinical study.

Technological Characteristics and Mode of Operation
The WP100S-2, like its predicate the WP100S, is a ventilatory effort recorder that utilizes PAT technology. The hardware of the WP100S-2 is basically identical to that of the WP100S except that the internal coating of the WP100S-2's PAT probe was modified to a non-latex coating. The WP100S-2's software modifications raise no new issue of safety or effectiveness, as demonstrated through software verification and validation and supportive clinical data.

Performance Testing
Software validation testing was conducted to evaluate both the performance of the WP100S-2 System and to verify that it performs according to its specifications described in the Software Requirements Specifications (SRS).
A clinical study was conducted to validate the accuracy of the WP100S-2 System in sleep staging identification and detection of respiratory related sleep disorders against both a gold-standard PSG and the predicate device (Biosleep for sleep staging identification and WP100S for respiratory disturbance index). The study results establish the accuracy of the WP100S-2 System in Sleep Staging identification. The study results additionally establish the accuracy of the WP100S-2 System in Sleep Apnea Indices (PRDI and PAHI).

Summary
Based on the performance testing results, including software verification and validation process and the analysis of the similarities and differences,

Itamar Ltd. believes that the WP100S-2 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
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 3 2008

Itamar Medical Limited
C/O Mr. Jonathan S. Kahan
Regulatory Affairs Consultant
Hogan & Hartson, L.L.P.
555 Thirteenth Street, NW
Washington, DC 20004-1109

Re: K080427
Trade/Device Name: Watch-PAT100S-2 (WP100S-2)
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II
Product Code: MNR
Dated: May 14, 2008
Received: May 14, 2008

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
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): K080427

Device Name: Watch-PAT100S-2 (WP100S-2)

Indications for Use:

The Watch-PAT100S-2 (WP100S-2) device is a non-invasive home care device for use with patients suspected to have sleep related breathing disorders. The WP100S-2 is a diagnostic aid for the detection of sleep related breathing disorders and sleep staging (Rapid Eye Movement (REM) Sleep, Light Sleep, Deep Sleep and Wake). The WP100S-2 generates a peripheral arterial tonometry ("PAT") Respiratory Disturbance Index ("PRDI"), Apnea-Hypopnea index ("PAHI") and PAT sleep staging identification (PSTAGES). The WP100S-2's PSTAGES provides supplemental information to its PRDI/PAHI. The WP100S-2's PSTAGES is 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.

The WP100S-2 is not indicated for children less than 17 years old.

Prescription Use __√__ 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)

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

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510(k) Number: K080427