DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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February 24, 2017

Itamar Medical, Ltd.
% Jonathan Kahan
Partner
Hogan Lovells US LLP
555 13th Street, NW
Washington, District of Columbia 20004-1109

Re: K161579
Trade/Device Name: Watch-PAT200U
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: Class II
Product Code: MNR
Dated: January 23, 2017
Received: January 23, 2017

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page

510(k) Number *(if known)*

K161579

Device Name

Watch-PAT200U

Indications for Use *(Describe)*

The Watch-PAT200U (WP200U) device is a non-invasive home care device for use with patients suspected to have sleep related breathing disorders. TheWP200U 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"), Central Apnea-Hypopnea index ("PAHIc"), PAT sleep staging identification (PSTAGES) and optional snoring level and body position discrete states from an external integrated snoring and body position sensor. The WP200U's PSTAGES and snoring level and body position provide supplemental information to its PRDI/PAHI/PAHIc. The WP200U's PSTAGES and snoring level and body position 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.

PAHIc is indicated for use in patients 17 years and older. All other parameters are indicated for 12 years and older.

Type of Use *(Select one or both, as applicable)*	
☒ Prescription Use (Part 21 CFR 801 Subpart D)	☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) SUMMARY

5.1 Applicant's Name: Itamar Medical ltd.
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5.2 Contact Person: Jonathan Kahn, Esq.
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5.3 Date Prepared: February 23, 2017

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:

- Primary Predicate Device: Watch-PAT200U ("WP200U") (Itamar Ltd), cleared under K133859; product code MNR (ventilatory effort recorder)
- Additional Predicate Device: Embla Systems' Embletta MPR Sleep Data Recording System (K122516)

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. TheWP200U 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"), Central Apnea-Hypopnea index ("PAHIc"), PAT sleep staging identification (PSTAGES) and optional snoring level and body position discrete states from an external integrated snoring and body position sensor. The WP200U's PSTAGES and snoring level and body position

provide supplemental information to its PRDI/PAHI/PAHIc. The WP200U's PSTAGES and snoring level and body position 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.

PAHIc is indicated for use in patients 17 years and older. All other parameters are indicated for 12 years and older.

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/RESBP (optional); (4) electronics, which include a controller that records the signals provided by the PAT finger probe, oximeter, actigraph and SBP/RESBP; (5) the device software; and (6) a power supply.

The subject WP200U introduces the RESBP sensor – an additional Snoring and Body Position (SBP) integrated sensor which also includes chest movement signal.

Another change in the subject WP200U is the introduction of new sleep disorder parameter - central apnea/hypopnea index (pAHIc).

5.15 Substantial Equivalence:

Intended Use

The intended use of the subject Watch-PAT200U (“WP200U”) is similar to the intended use of its predicate, the Watch-PAT200U (Itamar Ltd). The only difference is that the subject device provides new sleep disorder parameter - central apnea/hypopnea index (pAHIc). All other information supplied, are exactly the same as the predicate device. The additional information in the subject device does not alter the intended diagnostic use of the WP200U.

For the added capability of identification of central Apnea/Hypopnea events, the company selects additional predicate device - Embla Systems’ Embletta MPR Sleep Data Recording System (K122516) intended to assist in the identification of sleep-related medical disorders, including Central Sleep Apnea Syndrome.

Comparison of Technological Characteristics

The technological characteristics and principles of operation of the subject device are identical to the predicate device. The subject WP200U, like its predicate, is a ventilatory effort recorder that utilizes PAT technology. Specifically, the hardware and the software of the subject device are similar to that of the primary predicate device, except the following modifications:

1. RESBP sensor – an additional Snoring and Body Position (SBP) integrated sensor which also includes chest movement signal.
2. The algorithms of the primary predicate are further developed in the subject device to provide the information regarding central Apnea/Hypopnea events.

Please note that the pAHIc is presented only when the patient uses the RESBP sensor in the sleep study.

The subject device also has similar technological characteristics to the additional predicate Embletta. Although the subject device uses PAT signal to measure physiological parameters, this difference does not raise different types of safety and effectiveness questions. Specifically, the agency has cleared PAT signal in the primary predicate device.

The subject WP200U principle of operation is identical to the cleared WP200U principles of operation.

Performance Testing

Since there were no modifications to the WP200U predicate device K133859, consensus standards conducted on the predicate device is applicable to the subject device. The following consensus standards were used to evaluate the predicate device:

- Electrical safety and Electromagnetic compatibility testing per IEC 60601-1:2005 +C1:2006 +C2:2007 +AM1:2012, IEC 60601-1-2:2014, and 60601-1-11:2015
- Software verification and validation
- Bench testing to show that the snore intensity in decibels and body position discrete states measured by the new respiratory effort snore and body position (RESBP) sensor is the same as that measured by the cleared snore and body position (SBP) sensor.
- Clinical study was conducted to evaluate the WP200U's capability to identify central sleep apnea and Cheyne-Stokes Respiration. 72 subjects were evaluated in an overnight sleep study using the subject device and polysomnographic (PSG) manual scoring. Test results demonstrated substantially equivalent performance.

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

Summary

Based on the performance testing results, including the electrical and electromagnetic testing, clinical study, software verification and validation process and bench test, Itamar Ltd. believes that the WP200U System is substantially equivalent to its predicates.