DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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July 26, 2016

Itamar Medical, Ltd.
% Jonathan Kahan
Partner
Hogan Lovells US LLP
555 Thirteenth Street, NW
Washington, D.C. 20004

Re: K153070
Trade/Device Name: Watch-PAT200U ("WP200U")
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: Class II
Product Code: MNR
Dated: July 5, 2016
Received: July 5, 2016

Dear Jonathan 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,

Tejashri Purohit-Sheth, M.D.

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

Tina Kiang, PhD.
Acting Director
Division of Anesthesiology,
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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 below.

510(k) Number *(if known)*
K153070

Device Name
Watch-PAT200U ("WP200U")

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. 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.

The WP200U is indicated for use in patients 12 years of age or greater.

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

Itamar Medical's Watch-PAT200U

Submitter Information:

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Contact Person:	Jonathan Kahan Hogan Lovells US LLP 555 Thirteenth Street, NW Washington, DC 20004 Phone: (202) 637-5794 Fax: (202) 637-5910

Date Prepared: July 13, 2016

Subject Device:

Device Name:	Watch-PAT200U ("WP200U")
Common Name:	Ventilatory Effort Recorder
Classification Name:	Breathing Frequency Monitor
Regulation:	Class II, 21 C.F.R. § 868.2375
Product Code:	MNR

Predicate Devices:

Primary Predicate:	Itamar Medical's Watch-PAT200U (K133859)
Reference Device:	Embla Systems' Embletta MPR Sleep Data Recording System (K122516)

Indications 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.

The WP200U is indicated for use in patients 12 years of age or greater.

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.

Substantial Equivalence

Intended Use

The Watch-PAT200U is substantially equivalent to the primary predicate device K133859. Both devices have the same intended use as non-invasive, home-care devices for use with patients suspected to have sleep-related breathing disorders. The indications for use is identical to the predicate except for the modification of the device's intended use population to include patients 12 years of age or greater. FDA has cleared reference device Embla Systems' Embletta MPR Sleep Data Recording System (K122516) for the identification of sleep-related disorders in similar pediatric patient population.

Comparison of Technological Characteristics

The technological characteristics and principles of operation are identical between the subject device and the primary predicate device WP200U (K133859). They have identical hardware, software, materials, and components. There were no modifications to the PAT technology or the algorithm for the detection of sleep related breathing disorders in the predicate device for

the expanded pediatric patient population. The subject and primary predicate devices include the same recording channels: PAT, pulse rate, oximetry, actigraphy, optional snoring level, and 5 discrete body position states. The reference device (K122516) measures Electrocardiogram (EKG), Electroencephalogram (EEG), Electromyography (EMG), Electrooculogram (EOG), Resp, Thermistor and Pressure channels. The PAT technology was already cleared in the primary predicate device K133859 for the same intended use.

The subject device, primary predicate and reference device provide information concerning sleep-related disorders using sleep disordered breathing (SDB) indices – Respiratory Disturbance index (RDI) and Apnea/Hypopnea index (AHI), while the reference device provides also respiratory events classification. The supplementary functions of the reference device do not affect the safety and effectiveness of the subject device for its intended use.

Performance Data

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

- IEC 60601-1:2005 +C1:2006 +C2:2007 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2007 +CISPR11:2009 +A1:2010 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC 60601-1-11:2010 Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance -- Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- ISO 80601-2-61:2011 Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
- Software verification and validation testing was performed to demonstrate that the software in the subject device meets design specifications.

Also, no additional biocompatibility testing is required because the patient contacting materials are identical to the predicate.

A form-fit-function study was conducted to evaluate the WP200U in pediatric patients age range from 12 through 17 years old. The following were evaluated in the study:

- Use assessment (ease of sensor's placement and removal)
- Fit of sensor/strap
- Physiological effects on the measurement site (discomfort, sweating, pressure marks)
- SpO_2 accuracy compared to control (Transfer Standard Pulse Oximeter)

Clinical Data

Itamar has performed a clinical data assessment in the adolescent population to assure there are no new safety issues or performance concerns when including adolescent population in the WatchPAT's intended use. This assessment included the following activities:

1. **Literature review.** Itamar performed a broad search and analyzed peer reviewed articles and international guidelines concerning sleep medicine in the age group of 12 to 17 years old.
2. **Published study.** A published abstract assessing the use of the WP device in children was identified. Seventeen children with OSA (age range from 5 to 17 years old; 11 males and 6 females) underwent simultaneous recording of in-lab polysomnography and WatchPAT sleep study.
3. **Clinical studies to evaluate the subject device on adolescent patients**. Data from adolescence patients (12 to 17 years old) was pooled from 3 prospective clinical studies sponsored by Itamar of a broader age range population. The purpose of the studies was to compare the efficacy of the WP to the manual scoring of the PSG for aiding in the diagnosis of SDB. The effectiveness of the WP was determined by evaluating the correlation between the WP sleep indices and similar indices generated by the manual scoring of the PSG. The sensitivity and specificity of SDB were evaluated using the threshold of 10. The effectiveness of the WP's sleep stages was determined by evaluating its agreement to the sleep stages generated by the PSG. A subgroup analysis was performed on the relevant subjects' records. Their results were compared to the corresponding results in adult subjects gathered in a separate clinical study which had been previously submitted to the agency under 510(K) submission number K080427. Results showed that the PAHI in the adolescence population was highly correlated with the AHI measured by the PSG with $R = 0.92$, $p < 0.0001$. Using a threshold of 10 for PSG, sensitivity and specificity of the WP for adolescence were both 100.0%. The accuracy of sleep stages generated by the WP in the adolescence population showed an overall agreement of 64.6% versus the PSG. Kappa agreement was 0.51 (95% CI: 0.499 to 0.519) in the adolescence population.

Conclusions

Itamar believes that the subject device is substantially equivalent to the primary predicate device K133859. Both devices have the same intended use and indications for use with the exception of the expanded adolescent patient population. FDA has already cleared reference device Embla's Embletta MPR (K122516) for this pediatric patient population. Itamar did not make any modifications to the hardware or software of the primary predicate device. A form-fit-function study and clinical data demonstrated that the subject device has substantially equivalent performance in monitoring sleep disorders. Therefore, the subject device is substantially equivalent to the primary predicate device.

A summary of comparison between the subject and predicate devices is provided below.

	Subject Device: **Itamar Medical's Watch-PAT200U**	**Primary Predicate Device:** **Itamar Medical's Watch-PAT200U (K133859)**	**Reference Device:** **Embla's Embletta MPR (K122516)**
Indications 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. The WP200U is indicated for use in patients 12 years of age or greater.	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.	The Embletta MPR is a digital recording device designed to be used under the direction of a physician or trained technician but may be applied by a layperson. The Emblett a MPR records multiple physiological parameters from a sleeping patient for the purpose of simultaneous or subsequent display of the parameters. The displayed data assists in the identification of sleep-related medical disorders by trained personnel. The Embletta MPR is intended to be used for adult and pediatric (excluding infants and neonatal) studies. The device is not equipped with alarms and is not intended to be used as a monitor. The intended environments include any clean, dry, dust free environment suitable for a patient's relative comfort. The device does not monitor or diagnose the patient and does not issue any alarms.
User Population	Adult and adolescence (age range greater than 12 years old)	Adult patients suspected to have sleep related breathing disorders	Adult and pediatric (excluding infants and neonatal)
Intended Use Environment	Home Use	Home Use	Sleep clinics and home
recording signal capabilities	PAT, pulse rate, oximetry, actigraphy and an optional snoring level, 5 discrete body position states	PAT, pulse rate, oximetry, actigraphy and an optional snoring level, 5 discrete body position states	EKG, EEG, EMG, EOG, Pulse, Resp (ABD, Thorax), Thermistor, Oximetry, Pressure, Actigraphy, BP, Snore
Sleep-disordered breathing (SDB) indices	• pRDI (17 years of age and older) • pAHI	• pRDI • pAHI	• RDI • AHI (Obstructive / central and mixed) • Cheyne-Stokes Breathing

	Subject Device: **Itamar Medical's Watch-PAT200U**	**Primary Predicate Device:** **Itamar Medical's Watch-PAT200U (K133859)**	**Reference Device:** **Embla's Embletta MPR (K122516)**
Additional Sleep parameters output	• Sleep stages • Snoring level • Five Body position discrete states	• Sleep stages • Snoring level • Five Body position discrete states	• Sleep stages • Snoring • Five Body position discrete states • PLM • Arousal
Components	• uPAT finger probe • actigraph • Controller • Microphone • Accelerometer • ZzzPAT software • External SBP sensor (optional) • External Tamper-Proof Bracelet (optional)	• uPAT finger probe • actigraph • Controller • Microphone • Accelerometer • ZzzPAT software • External SBP sensor (optional) • External Tamper-Proof Bracelet (optional)	• Unit recorder • Recorder • oximeter • Thermistor and nasal canula • Sensors (snoring, body position) • respiratory effort belts • electrodes (EEG, EOG, EMG, EKG) • RemLogic Software software
Power Supply	Proprietary, rechargeable Li Ion Battery	Proprietary, rechargeable Li Ion Battery	Battery operated (2 AA)