August 17, 2018

Itamar Medical, Ltd.
% Mr. Jonathan Kahan
Partner
Hogan Lovells US, LLP
555 Thirteenth Street, NW
Washington, District of Columbia 20004

Re: K180775
Trade/Device Name: Watch-PAT300
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: Class II
Product Code: MNR
Dated: July 18, 2018
Received: July 18, 2018

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Amy K. Levelle -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Watch-PAT300 (WP300)

Indications for Use *(Describe)*

The Watch-PAT300 (WP300) device is a non-invasive home care device for use with patients suspected to have sleep related breathing disorders. The WP300 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 WP300 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 WP300's PSTAGES and snoring level and body position provide supplemental information to its PRDI/PAHI/PAHIc. The WP300'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 Kahan, Esq.
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5.3 Date Prepared: August 17, 2018

5.4 Trade Name: Watch-PAT 300 ("WP300")

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 Device:

Watch-PAT200U ("WP200U") (Itamar Ltd), cleared under K161579; product code MNR (ventilatory effort recorder)

5.13 Intended Use / Indication for Use:

The Watch-PAT300 (WP300) device is a non-invasive home care device for use with patients suspected to have sleep related breathing disorders. The WP300 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 WP300 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 WP300's PSTAGES and snoring level and body position

provide supplemental information to its PRDI/PAHI/PAHIc. The WP300'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-PAT300 System (WP300) is a non-invasive home care device for use with patients suspected to have sleep related breathing disorders. The WP300 is a diagnostic aid for the detection of sleep related breathing disorders (RDI, AHI and AHIc) and sleep staging (REM Sleep, Light Sleep, Deep Sleep and Wake) based on Peripheral Arterial Tonometry (PAT), a non-invasive technology. The WP300 can be connected to an external integrated sensor snoring and body position (SBP/RESBP) for recording snoring, body position and chest movement (in RESBP sensor only) data.

The WP300 device consists of the following: (1) Same unified finger PAT probe that was used in WP200U is used to measure the PAT and oximeter signals; (2) an embedded actigraph which provides a signal that is used to determine periods of sleep/wake based on the motion of the wrist; (3) Electronics, which include a microprocessor that records the information supplied by the uPAT finger probe, actigraph and chest movement; (4) snoring and body position sensor (SBP/RESBP sensors same sensors as in the WP200U) and (5) the device software.

The subject WP300 is an improved version of the predicate WP200U device (K161579) and introducing hardware changes to its components and new external design. The modifications made in order to upgrade the hardware (HW) components of the device, reduce the size of the WP200U device, improve the data download speed of the device, modify the materials in the wrist strap and update the device appearance. None of these changes alter the fundamental operation of the device or its principles of operation. Moreover, the modified system, the WP300 maintains the full capabilities of the cleared WP200U (K161579) and provides the user with the same output information, i.e. pRDI, pAHI, pAHIc, pSTAGES, snoring and body position, remain the same.

5.15 Substantial Equivalence:

Intended Use/Indications for Use

The intended use and the indications for use of the subject Watch-PAT300 are exactly the same as the cleared WP200U predicate device.

Comparison of Technological Characteristics and principle of operation

The technological characteristics and principles of operation of the subject device are similar to the predicate device. The subject WP300, like its predicate, is a ventilatory effort recorder that utilizes PAT technology. In both

systems, the controller part of the device is worn on the wrist, and records the PAT signal and blood oxygen saturation levels by a finger-mounted probe based on an optical plethysmographic method, and the wrist motion from an embedded actigraphy.

The hardware modifications do not alter the fundamental technology of the device. There were no modifications to the PAT technology or the algorithms for the detection of sleep related breathing disorders and sleep staging. The modified acquisition system was designed and verified to give the same input signals to the algorithm as the predicate WP200U.

The subject WP300 principle of operation is similar to the predicate device principles of operation. The power supply modification introduced in the WP300 did not alter the fundamental principle of operation of the device. In the predicate WP200U, the battery is internal to the device and was charged after each use using the AC adaptor. In the WP300, a new or fully charged battery is required instead of charging the battery as in the WP200U.

Performance Testing

The following consensus standards were used to evaluate the predicate device:

- Bench testing was conducted to verify that the performance characteristics of the device were not affected as a result of the modifications described above by demonstrating the equivalency of the WP300 signals to the cleared WP200U signals.
- Electrical safety testing per IEC 60601-1:2005 + CORR.1 (2006) + CORR.2 (2007) and AM1:2012
- Electromagnetic compatibility testing per IEC 60601-1-2:2014
- Home healthcare environment per 60601-1-11:2015
- Cytotoxicity, irritation and sensitization testing of the new wrist strap materials. All biocompatibility tests on the new materials passed.
- Software verification and validation testing was performed to demonstrate that the software in the subject device meets design specifications.
- Clinical testing was conducted to evaluate the SpO_2 accuracy and performance of the WP300 during non-motion conditions over the range of 70-100% SaO_2 to arterial blood samples assessed by CO-Oximetry for SpO_2 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 SpO_2 accuracy performance of the WP300 pass an A_{rms} specification of ≤3 under steady state and non-motion conditions for the range of 70-100%.

The testing above demonstrated that the WP300 is substantially equivalent to its predicate and the proposed modifications do not raise any different questions of safety or effectiveness.

Summary

Based on the performance testing results, including bench testing, electrical and electromagnetic testing, software verification and validation process and clinical testing, Itamar Ltd. believes that the WP300 System is substantially equivalent to its predicate.

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

	WP200U	**WP300**
Intended 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"), 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	Identical except for the device name
Channels	PAT, Pulse rate, Oximetry, Actigraphy, Snoring (optional), Body Position (optional), Chest Movement (optional)	Identical
Analysis output	• pRDI • pAHI • pAHIc • Sleep stages • Snoring level • Body position discrete states	Identical
Input uPAT Probe	Designed to use Itamar proprietary probe only	Identical

	WP200U	WP300
Components	• uPAT finger probe • actigraph • Controller • Microphone • Accelerometer • Wrist strap • ZzzPAT software • External SBP / RESBP sensor (optional) • External Tamper-Proof Bracelet (optional)	Identical except for the new materials in the wrist strap. Complete biocompatibility testing was conducted on the new materials and passed.
Sensors Placement	Wrist, finger and chest (optional)	Identical
Analysis Software	zzzPAT	Identical
Power Supply	Proprietary, rechargeable Lithium Ion Battery	One OTS 1.5V Alkaline AAA battery **OR** One rechargeable AAA 1.2V Nickel-metal hydride battery rechargeable (NiMH) battery