June 5, 2019

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

Re: K183559
Trade/Device Name: WatchPAT™ ONE (WP1)
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: Class II
Product Code: MNR
Dated: May 3, 2019
Received: May 3, 2019

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. 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Michael Ryan
Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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)*

K183559

Device Name
WatchPAT™ONE (WP1)

Indications for Use *(Describe)*

The WatchPAT™ONE (WP1) device is a non-invasive home care device for use with patients suspected to have sleep related breathing disorders. The WP1 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 WP1 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 snoring level and body position discrete states from an external integrated snoring and body position sensor. The WP1's PSTAGES and snoring level and body position provide supplemental information to its PRDI/PAHI/PAHIc. The WP1'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: December 20, 2018

5.4 Trade Name: WatchPAT^{TM}ONE (WP1)

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-PAT 300 ("WP300") (Itamar Ltd), cleared under K180775; product code MNR (ventilatory effort recorder)

5.13 Intended Use / Indication for Use:

The WatchPAT™ONE (WP1) device is a non-invasive home care device for use with patients suspected to have sleep related breathing disorders. The WP1 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 WP1 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 snoring level and body position discrete states from an external integrated snoring and body position sensor. The WP1's PSTAGES and snoring level and body position provide

supplemental information to its PRDI/PAHI/PAHIc. The WP1'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 WatchPAT™ONE (WP1) is a non-invasive home care device intended for use with patients suspected to have sleep related breathing disorders. The WP1 generates a PAT respiratory disturbance index (PRDI), Apnea Hypopnea Index (PAHI), Central Apnea Hypopnea Index (PAHIc), sleep stages (PSTAGES - REM Sleep, Light Sleep, Deep Sleep and Wake) and snoring level and body position discrete states.

The WP1 device consists of the following: (1) same unified finger PAT probe that was used in WP300 to measure the PAT and oximeter signals; (2) same Actigraph which provides a signal that is used to determine periods of sleep/wake based on the motion of the wrist; (3) same electronics, except for an antenna added in the WP1's PCB to support BLE communication; (4) same chest sensor (RESBP) to measure snoring level, body position and chest movements; and (5) same zzzPAT Software and algorithm to analyze the data.

The subject WP1 is a modified version of the predicate WP300 device (K180775). The proposed modifications mainly include: transition from a reusable device to a single use device; shifting the display and user interface from the device to a mobile application; and shifting of the data storage from main device to a web server. None of these changes alter the fundamental technology or its principles of operation. Moreover, the WP1 maintains the same capabilities of the cleared WP300 (K180775) and provides the user with the same output information.

5.15 Substantial Equivalence:

Intended Use/Indications for Use

The subject device WP1 is identical to the cleared WP300 in its intended use and indications for use, except for the minor modification of omitting the word 'optional' from the use of snoring and body position sensor (RESBP sensor).

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 WP1, 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, the wrist motion from an embedded actigraphy and snoring level, body position states and chest movements from the chest sensor (RESBP).

The WP1 mainly differs from the WP300 by combining the key components into an undetachable monolith device. A mobile application also replaced the predicate WP300's user interface and communication. The WP1's monolithic package uses the same hardware as the predicate WP300 to measure patient data. In addition, the user interface of the mobile application was designed to provide similar display and input as the WP300. Although the patient data is transmitted and stored on a Web Server, the integrity of the patient data can be verified and validated. Furthermore, the cybersecurity risks were addressed according to FDA's cybersecurity guidance document[1]. As such, the differences in technological characteristics and principle of operation do not raise different questions of safety or effectiveness.

Performance Testing

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

- Bench test was conducted to show that the data acquired on the WP1 is identical to the data downloaded by zzzPAT at the physician computer.
- The WP1 was tested to ensure that the device complies with the Federal Communications Commission (FCC) rules.
- 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 housing and wrist strap materials.
- Software verification and validation testing was performed to demonstrate that the software in the subject device meets design specifications.

The testing above demonstrated that the WP1 has substantially equivalent performance as its predicate.

Summary

Based on the comparison of intended use, indications for use, technological characteristics and performance testing, Itamar Ltd. believes that the WP1 System is substantially equivalent to its predicate.

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

[1] FDA guidance document title, "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices", issued on October 2, 2014

	Predicate Device: Itamar Medical's Watch-PAT300 (K180775)	Subject Device: Itamar Medical's WP1	Comparison
Intended 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	The WatchPAT™ONE (WP1) device is a non-invasive home care device for use with patients suspected to have sleep related breathing disorders. The WP1 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 WP1 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 snoring level and body position discrete states from an external integrated snoring and body position sensor. The WP1's PSTAGES and snoring level and body position provide supplemental information to its PRDI/PAHI/PAHIc. The WP1'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 device name and omission of the word 'optional'
Channels	PAT, Pulse rate, Oximetry, Actigraphy, Snoring, Body Position, Chest Movement	PAT, Pulse rate, Oximetry, Actigraphy, Snoring, Body Position, Chest Movement	Identical
Intended Use Environment	Home Use	Home Use	Identical
Input uPAT Probe	Designed to use Itamar proprietary probe only	Designed to use Itamar proprietary probe only	Identical
Analysis output	• pRDI • pAHI • pAHIc • Sleep stages • Snoring level • Body position discrete states	• pRDI • pAHI • pAHIc • Sleep stages • Snoring level • Body position discrete states	Identical

	Predicate Device: Itamar Medical's Watch-PAT300 (K180775)	Subject Device: Itamar Medical's WP1	Comparison
Components	• uPAT finger probe • actigraph • Controller • Microphone • Accelerometer • ZzzPAT software • Chest sensor (optional) • External Tamper-Proof Bracelet (optional)	• uPAT finger probe • actigraph • Controller • Microphone • Accelerometer • ZzzPAT software • Chest sensor	Chest sensor was already cleared in the predicate. Optional tamper-proof bracelet for identification of a patient by means of electronic bracelet is not available in WP1.
Sensors Placement	Wrist, finger and chest (optional)	Wrist, finger and chest	Identical
Analysis Software	zzzPAT	zzzPAT	Identical
Power Supply	One OTS 1.5V Alkaline AAA battery OR One rechargeable AAA 1.2V Nickel-metal hydride battery rechargeable (NiMH) battery	One OTS 1.5V Alkaline AAA battery	Single use battery only
Data Access Method	USB using FTDI	Internet access using sFTP protocol	Same data delivered to the analysis software zzzPAT
Data Collection	• Sensors connect direct to main device. • Study data is stored on the main device and then uploaded via USB cable upon return of the device.	• Sensors connect direct to main device. • Study data is wirelessly transferred (Bluetooth) from main device to mobile phone and from the mobile phone to a storage on a web server, over the Internet.	Same data delivered to the analysis software zzzPAT
Data Storage	Flash	Web Server	Data is stored in web server instead of on-board flash memory.
Recording time	Approx. 10 hours	Approx. 10 hours	Identical
Motion Probe	1 axis (out of 3D accelerometer)	1 axis (out of 3D accelerometer)	Identical
Analog Front End	AFE4404 (by TI)	AFE4404 (by TI)	Identical
Microprocessor	Nordic ARM	Nordic ARM	Identical
Sample Resolution	PAT, Actigraphy, Snore: 12 bits Oximetry: 1% Body Position: 5 discrete states (supine, prone, right, left and sit) Chest Movements – 12 bits x 3 axis	PAT, Actigraphy, Snore: 12 bits Oximetry: 1% Body Position: 5 discrete states (supine, prone, right, left and sit) Chest Movements – 12 bits x 3 axis	Identical
Operating Voltage	3.3 V	3.3 V	Identical
User Interface Display/ Indicators	Via Main device: OLED	Via Smartphone User Interface Via Main device (LED)	Similar user display and input