January 6, 2023

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

Re: K223675
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: December 7, 2022
Received: December 7, 2022

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,

Rachana Visaria -S

Rachana Visaria, Ph.D.
Assistant Director
DHT1C: Division of Sleep Disordered
Breathing, Respiratory and
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223675

Device Name
WatchPAT ONE (WP1)

Indications for Use *(Describe)*
The WatchPAT ONE (WP1) device is a noninvasive 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 optional 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

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Date Prepared: November 30th, 2022

Trade Name: WatchPAT ONE (WP1)

Common or Usual Name: Ventilatory Effort Recorder

Classification Name: Breathing Frequency Monitor

Medical Specialty: Anesthesiology

Product Code: Ventilatory Effort Recorder, MNR

Device Class: Class II

Regulation Number: 868.2375

Panel: Anesthesiology

Predicate Device: WatchPAT300 (WP300) (Itamar Medical Ltd), cleared under K222331; product code MNR

Reference Device: WatchPAT ONE (WP1) (Itamar Medical Ltd.), cleared under K183559; product code MNR

Purpose of the Special 510(k) notice.

The subject WP1 combines the software arrhythmia feature of the predicate device WP300 (K222331) into the reference device WP1 (K183559).

Intended Use

The WatchPAT ONE 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 optional 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.

Device Description

The subject WatchPAT ONE (WP1) has the same intended use and indications for use as the cleared predicate WP300 (K222331) and the cleared reference WP1 (K183559). The subject WP1 combines the software arrhythmia feature of the WP300 cleared predicate (K222331) into the WP1 cleared reference (K183559).

The subject WP1 consists of: A wrist worn Control Unit, Actigraphy (in the Control Unit), Wrist Strap, Power Supply (battery), uPAT probe, Chest sensor (optional), Management and Analysis Software (SW) and mobile application.

The subject WP1, like the predicate WP300 and reference WP1, uses the same Management and Analysis Software (SW). The arrhythmia feature is to be used for informational use only, to flag patients suspected of having arrhythmias, thereby aiding the physician to decide if further arrhythmia investigation is needed. The device is not intended to be used as a diagnostic device for cardiac arrhythmia and it is not intended to replace traditional methods of diagnosis. The arrhythmia detection is not intended for use in life supporting or sustaining systems or monitor and alarm devices. It provides the sleep physician with additional information to that of the WP1 cleared capabilities of detecting sleep disorders, to be considered in conjunction with the physician’s knowledge of patient background, clinical history, symptoms, and other diagnostic information.

Technological Characteristics

The subject WP1 has the same technological characteristics as the predicate WP300 and the reference WP1 to which it has been modified.

Identically to WP300 and WP1, the subject WP1 device is a ventilatory effort recorder that utilizes Peripheral Arterial Tone (PAT) signal. It is a patient-worn device used at home for aiding in the diagnosis of sleep related breathing disorders based on the PAT signal. In all 3 systems, the controller part of the device is worn on the wrist and records the PAT signal and blood oxygen saturation levels in the distal part of the finger by a finger-mounted probe based on an optical plethysmographic method, and the wrist motion from an embedded actigraphy.

The following report output information is provided by the cleared WP300, cleared WP1, and the subject WP1 using the same offline SW and algorithms that analyze recorded data to present respiratory disturbance index (pRDI), Apnea Hypopnea Index (pAHI), Central Apnea Hypopnea Index (pAHIc), sleep stages (pSTAGES - REM Sleep, Light Sleep, Deep Sleep, Wake), snoring level and body position discrete states. The new arrhythmia information in the subject WP1's report is identical to the one in the cleared predicate WP300.

The subject WP1, identically to both the predicate and the reference device, consists of the same components: (1) unified PAT probe (uPAT) is used to measure the PAT and oximetry 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; and (4) chest sensor (SBP/RESBP sensors same as in the predicates).

The SW characteristics of the subject WP1 and the reference WP1 are the same except for the newly added SW algorithm that was cleared for use in the predicate WP300 (K222331) to identify or 'flag' the patient for further arrhythmia investigation (Atrial Fibrillation and Premature Beats). This additional SW algorithm is the proposed modification to the subject WP1.

The HW of the subject WP1 is the same as the HW of the reference WP1 (K183559). Further, the HW of the WP1 was designed to provide identical signals to that of the predicate WP300. The differences in HW between the WP1 and the WP300 devices have been thoroughly discussed and found to be substantially equivalent in K183559.

The cleared arrhythmia SW algorithm from the predicate WP300 added to the subject WP1 does not alter the technological characteristics of the device or its principles of operation.

Performance Data

SW Design verification was performed on the subject WP1 device with the SW containing the additional arrhythmia feature. The testing and acceptance criteria are the same as those in the predicate WP300 and reference WP1 devices. Bench testing was previously conducted on the reference WP1 (K183559) to show that the acquisition system of the WP1 and WP300 generate equivalent input signals to the analysis algorithms. Specifically, the equivalence of the PAT and the actigraphy signals which are used in the newly added arrhythmia algorithm were tested. This testing provides evidence that the WP1 signals are equivalent to the WP300 signals.

Substantial Equivalence

The subject WP1 has the same intended use as both the predicate WP300 and the reference WP1. The WP1's new SW arrhythmia feature is offered as supplemental information to its sleep information. The device is not intended to be used as a diagnostic device for any cardiac arrhythmia. All other information supplied is the same as the information supplied by the predicate device and the differences in HW between the predicate WP300 (in which the new SW feature for Arrhythmia detection was cleared) and the subject WP1 do not raise new questions of safety or effectiveness.

	Subject WP1	WP300 (K222331)	WP1 (K183559)	Comparison
Intended 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 **optional** 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	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.	Same as WP300, almost the same as WP1 reference device, except for addition of the word “optional”, highlighted in bold.
User Population	Adult and adolescence (from age 12)	Adult and adolescence (from age 12)	Adult and adolescence (from age 12)	Same
Intended Use Environment	Home Use	Home Use	Home Use	Same

	Subject WP1	WP300 (K222331)	WP1 (K183559)	Comparison
Channels	PAT, Pulse rate, Oximetry, Actigraphy, Snoring, Body Position, Chest Movement	PAT, Pulse rate, Oximetry, Actigraphy, Snoring, Body Position, Chest Movement	PAT, Pulse rate, Oximetry, Actigraphy, Snoring, Body Position, Chest Movement	Same
SW Analysis output	• Respiratory indices (pRDI, pAHI,pAHIc) • Sleep stages (REM, light, deep and wake) • Snoring level • Body position discrete states • Heart rate statistics • Oximetry statistics	• Respiratory indices (pRDI, pAHI,pAHIc) • Sleep stages (REM, light, deep and wake) • Snoring level • Body position discrete states • Heart rate statistics • Oximetry statistics	• Respiratory indices (pRDI, pAHI,pAHIc) • Sleep stages (REM, light, deep and wake) • Snoring level • Body position discrete states • Heart rate statistics • Oximetry statistics	Same
	Arrhythmia flagging output: • Suspected Atrial Fibrillation (AFib): o Total duration in sleep o Longest event duration • Premature beats: o Events per minute	Arrhythmia flagging output: • Suspected Atrial Fibrillation (AFib): o Total duration in sleep o Longest event duration • Premature beats: o Events per minute	No Arrhythmia output	Same as WP300
Input uPAT Probe	Itamar proprietary probe only	Itamar proprietary probe only	Itamar proprietary probe only	Same
HW Components	• uPAT finger probe • Actigraph • Controller • Chest sensor (optional)	• uPAT finger probe • Actigraph • Controller • Chest sensor (optional) • External Tamper-Proof Bracelet (optional)	• uPAT finger probe • Actigraph • Controller • Chest sensor	Same except optional Tamper Proof Bracelet not available in WP1, and chest sensor was not optional in predicate WP1.
Power Supply	One OTS 1.5V Alkaline AAA battery	One OTS 1.5V Alkaline AAA battery OR One rechargeable AAA 1.2V Nickel-metal hydride (NiMH) battery	One OTS 1.5V Alkaline AAA battery	Same as WP1, single use battery only
Sensors Placement	Wrist, finger and chest (optional)	Wrist, finger and chest (optional)	Wrist, finger and chest	Same, except for chest not being optional in predicate WP1
Intended user of the Arrhythmia output	Physician	Physician	No Arrhythmia output	Same as WP300
Arrhythmia Monitoring period	During prescribed sleep study	During prescribed sleep study	No Arrhythmia output	Same as WP300
Arrhythmia output technological characteristic	PPG	PPG	No Arrhythmia output	Same as WP300

Conclusions

The subject WP1 has the same technological characteristics and principles of operation as its predicates and the new SW arrhythmia feature does not raise any new questions of safety or efficacy. Substantial equivalence of the subject device has been proven towards the predicate, and the differences in HW between the WP300 (from which the new SW feature for Arrhythmia detection was cleared) and the subject WP1 do not raise new questions of safety or effectiveness. Thus, the subject WP1 is substantially equivalent. Based on the above Itamar Medical Ltd. concludes that the WP1 is substantially equivalent to its predicate and does not raise any new or different concerns about safety or effectiveness.