March 21, 2022

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

Re: K203839
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: February 17, 2022
Received: February 17, 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, Ph.D.
Assistant Director
DHT1C: Division of 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)*
K203839

Device Name
Watch-PAT200U (WP200U)

Indications for Use *(Describe)*
The WatchPAT™200U (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.

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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K203839 - 510(K) SUMMARY

Applicant's Name: Itamar Medical ltd.
9 Halamish st.
Caesarea 3088900, Israel
Tel: +972 4 617 7000
Fax: +972 4 627 5598

Contact Person: Jonathan Kahan, Esq.
Hogan Lovells US LLP
Columbia Square
555 Thirteenth Street, NW
Washington, DC 20004-1109
Tel: (202)637-5794
Fax: (202)637-5910
Email: jonathan.kahan@hoganlovells.com

Date Prepared: March 21, 2022

Trade Name: Watch-PAT200U (WP200U)

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 Devices:

- Primary predicate: Watch-PAT200U ("WP200U") (Itamar-Medical), cleared under K161579; product code MNR (ventilatory effort recorder).
- Reference device: Compumedics Somté PSG System (Compumedics), cleared under K072201; product code MNR (ventilatory effort recorder)
- Reference device: Melys Atrial Fibrillation Monitor (Advanced Fluidics), cleared under K132206; product code DXH (Transmitters and Receivers, Electrocardiograph, Telephone)

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. 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.

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 (pRDI), apnea - hypopnea index (pAHI), central apnea - hypopnea index (pAHIc) and sleep staging (Rapid Eye Movement (REM), Light Sleep, Deep Sleep and Wake) based on Peripheral Arterial Tonometry (PAT), a non-invasive technology. In accordance with physician discretion, the WP200U may be connected to a chest sensor for measuring snoring level, body position states and chest movements.

The WP200U device consists of the following: (1) unified finger PAT probe to measure PAT and oximeter signals; (2) actigraph, which provides a signal that is used to determine periods of sleep/wake based on the motion of the wrist; (3) chest sensor to measure snoring level, body position and chest movements (optional); (4) electronics, which include a controller that records the signals provided by the uPAT finger probe, actigraph and chest sensor; (5) tamper-Proof Bracelet (Optional); (6) power supply; (7) Wrist strap and (8) Management and Analysis Software Program.

The subject WP200U introduces new algorithms to its software allowing the identification of arrhythmia events occurred during the night - Atrial Fibrillation and Premature Beats.

Beside the introduction of the new arrhythmia information, the SW provides identical output information as that previously provided for the predicate.

The additional arrhythmia information presented by the modified WP200U device follows the AASM (American Academy of Sleep Medicine) guidelines to provide the sleep physician with information regarding cardiac events occurred during the night. The WP200U 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 WP200U's arrhythmia detection is not intended for use in life supporting or sustaining systems or monitor and alarm devices.

The new analysis provides the sleep physician with additional information to that of the WP200U 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.

Substantial Equivalence:

Intended Use

The intended use of the subject Watch-PAT200U ("WP200U") remains exactly the same as the intended use of its predicate, the WP200U (K161579) as a home device for diagnosis of sleep related breathing disorders.

The WP200U's new analysis of cardiac arrhythmia 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.

For the added capability of identifying arrythmia during sleep, the company selected a reference device, Somté PSG System, cleared under K072201 intended for recording physiological parameters to aid in the diagnosis of respiratory and/or cardiac related sleep disorders by qualified physicians. The Somté includes an analysis package for arrhythmia detection and classification ('ECG Analysis package'). It also provides ECG statistics during respiratory events and R-R interval (heart rate).

The intended use statement as previously cleared in K161579 was not changed and this capability of providing information regarding the cardiac arrythmia events is specified in the labeling of the subject device and does not raise additional or new questions of safety or effectiveness.

Comparison of Technological Characteristics with the predicate device

	Itamar Medical's Watch-PAT200U (Subject device)	**Primary predicate - Itamar Medical's Watch-PAT200U (K161579)**	**Reference - Compumedics's Somté (K072201)**	**Reference - Melys atrial fibrillation monitor (K132206)**	**Comparison**
Product Code	MNR	MNR	MNR	DXH	
Manufacturer	Itamar Medical	Itamar Medical	Compumedics	Advanced Fluidics, LLC	
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"), 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	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	The Somté PSG is intended for use in the recording, displaying, analysis, printing and storage of human biological parameters such as heart and muscle activity, eye movement, breathing and body movements to assist in the diagnosis of various sleep disorders or sleep related respiratory or cardiac disorders. The Somté PSG is designed for ambulatory and mobile operation and can be used in either the patient's home, the hospital or other environments, thus enabling patients to be investigated under as realistic conditions as possible. The Somté PSG is only to be used under the direction of a physician.	The Melys Atrial Fibrillation Monitor is indicated for self-testing by patients, who have been diagnosed with, or are susceptible to developing, atrial fibrillation and who would like to monitor and record their heart rhythms on an intermittent basis.	Substantially Equivalent to the predicate (Watch-PAT200U) - the intended use remains a diagnostic device to detect sleep related breathing disorders. For the added capabilities of arrhythmia output, as specified in the labeling, the WP200U is equivalent to the reference device - Somté system.

	Itamar Medical's Watch-PAT200U (Subject device)	Primary predicate - Itamar Medical's Watch-PAT200U (K161579)	Reference - Compumedics's Somté (K072201)	Reference - Melys atrial fibrillation monitor (K132206)	Comparison
	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	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			
User Population	Adult and adolescence (from age 12)	Adult and adolescence (from age 12)	Adult	Adult	Identical to primary predicate WP200U
Intended Use Environment	Home Use	Home Use	Hospitals and home use	Home Use	Identical
Channels	PAT, pulse rate, oximetry, actigraphy, snoring, body position, chest movement	PAT, pulse rate, oximetry, actigraphy, snoring, body position, chest movement	ECG, EEG, EOG, Respiratory signals, position	PPG	Identical to primary predicate WP200U To show equivalent in technology for arrhythmia output: Melys uses Photoplethysmography method

	Itamar Medical's Watch-PAT200U (Subject device)	Primary predicate - Itamar Medical's Watch-PAT200U (K161579)	Reference - Compumedics's Somté (K072201)	Reference - Melys atrial fibrillation monitor (K132206)	Comparison
					to detect atrial fibrillation from the finger.
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 □ Sleep stages □ Arousal detection □ PLM □ Snores □ Position □ Heart rate statistics □ Oximetry statistics □ Potential Bruxism		All analysis output provided in the subject WP200U is also provided in the primary predicate device. The new arrhythmia analysis did not alter or influence the respiratory indices and sleep stage generated by the WP200U Software.
	Arrhythmia flagging output: Suspected Atrial Fibrillation (AFib): • Total duration in sleep • Longest event duration Premature beats: • Events per minute	No arrhythmia output	ECG analysis software: • Automatic analysis with statistics and histograms • QRS complex classification • Arrhythmia detection and classification • ECG statistics during respiratory events • Trend data for ST segment and normal • R-R interval (heart rate) • Heart rate variability analysis • 24 hour ECG with full disclosure trace	Alerts user of an irregularity in their pulse, specifically AFib, through a light indicator.	Subset to Somté reference device. The Somté includes additional cardiac disorder outputs which the WP200U does not include.

	Itamar Medical's Watch-PAT200U (Subject device)	Primary predicate - Itamar Medical's Watch-PAT200U (K161579)	Reference - Compumedics's Somté (K072201)	Reference - Melys atrial fibrillation monitor (K132206)	Comparison
			display and printing ECG template classification and editing		
Components	□ uPAT finger probe □ Actigraph □ Controller □ Microphone □ Accelerometer □ Analysis software □ Chest sensor (optional) □ External Tamper-Proof Bracelet (optional) □ Software Program	□ uPAT finger probe □ Actigraph □ Controller □ Microphone □ Accelerometer □ Analysis software □ Chest sensor (optional) □ External Tamper-Proof Bracelet (optional) □ Software Program	□ Respiratory Effort Channels - Abdomen and Thorax □ Airflow □ Pressure □ Snore □ Body position □ SpO2 □ Pulse Rate □ Pulse wave □ ECG □ EEG/EMG/EOG	□ Atrial Fibrillation Monitor □ Finger Sensor (K101692)	Identical to primary predicate WP200U
Sensors Placement	Wrist, finger and chest (optional)	Wrist, finger and chest (optional)	Wrist, finger, face, leg, chest and abdomen	finger	Identical to primary predicate WP200U. In addition, both the WP200U and the reference device use a finger PPG sensor to detect atrial fibrillation
Intended user of the Arrhythmia output	Physician	No arrhythmia output	Physician	End user (self-testing by user)	Identical to Somte reference device
Arrhythmia monitoring period	During prescribed sleep study	No arrhythmia output	During prescribed sleep study	Spot check during wake (recommended 4 consecutive measurements of 10 seconds)	Identical to Somte reference device

	Itamar Medical's Watch-PAT200U (Subject device)	Primary predicate - Itamar Medical's Watch-PAT200U (K161579)	Reference - Compumedics's Somté (K072201)	Reference - Melys atrial fibrillation monitor (K132206)	Comparison
Arrhythmia output technological characteristic	PPG	No arrhythmia output	ECG	PPG	Both the subject and the reference device, Melys, device use PPG technology for arrhythmia output

The technological characteristics and principles of operation of the subject device are identical to the predicate WP200U device (K161579). The subject WP200U, like its predicate, is a ventilatory effort recorder that utilizes PAT™ (Peripheral Arterial Tone) technology. Both devices utilize a patient-worn device used at home for aiding in the diagnosis of sleep related breathing disorders based on the PAT signal.

The technological characteristics for the following elements are identical between the subject and predicate devices:

- A wrist worn Control Unit with actigraphy
- Finger Probe (uPAT probe) based on optical plethysmography that records:
    - PAT^{TM} signal
    - Arterial blood oxygen
- Chest sensor (SBP/RESBP) that measures:
    - Snoring level
    - Body position states
    - Chest movement
- Tamper-Proof Bracelet (Optional)
- Power Supply (battery/charger)

The difference between the subject device and the predicate:

- Modification within the Management and Analysis Software of the subject device: The software of the subject device is similar to that of the primary predicate device, except for the introduction of a new algorithm to identify episodes of irregular heart rhythms - Atrial Fibrillation (AFib) and Premature beats. The subject device utilizes the same technological characteristics, but with different SW analysis of the signals for the newly added SW feature.
- The subject device also has similar technological characteristics to the reference device Melys Atrial Fibrillation Monitor device ("Melys") cleared under

K132206, a portable device for measuring and displaying heart rate irregularity and pulse rate using PPG technology. The reference device is used to support the use of PPG technology from a finger sensor to provide information regarding heart rate irregularity and that these differences do not raise new questions of safety and effectiveness.

The subject WP200U principle of operation is identical to the primary predicate devices' principles of operation.

Note: While the WP200U uses PAT technology utilizing PPG to determine heart rhythm and the reference uses ordinary PPG, these changes do not affect the heart rate. The unique feature of the PAT is the use of a uniform pressure field which helps to avoid venous pooling, artifacts and improve signal's dynamic range.

Performance Testing

A series of safety and performance testing were performed. These tests include:

Electrical Safety and Electromagnetic Compatibility
Electrical safety and EMC testing were conducted on the WatchPAT200U device. The system complies with the IEC 60601-1:2005 + CORR.1 (2006) + CORR.2 (2007) and AM1:2012 for Safety, and IEC 60601-1-2:2014 for EMC.

Electrical Safety for Home Healthcare Environment
Electrical safety testing for the home healthcare environment was conducted on the WatchPAT200U device. The system complies with the IEC 60601-1-11 Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.

Software Verification and Validation Testing
Software verification and validation testing was performed to demonstrate that the software in the subject device performs according to its specifications. The software for this device was considered as a "moderate" level of concern since a failure or latent flaw could indirectly result in minor injury to the patient or operator through incorrect or delayed information or through the action of a care provider.

Clinical Testing
Clinical performance testing was performed to evaluate the capability of WP200U To identify arrhythmic events: Atrial fibrillation and premature beats, by comparing the subject device against "Gold Standard" cardiologist-scored ECG channel of a polysomnography (PSG). One hundred and fifty-seven (157) subjects were evaluated in an overnight sleep study using the subject device and a single-lead ECG recorded by a

PSG system in a sleep lab. Overall, the test results demonstrated acceptable performance of the subject device in detecting clinically relevant arrhythmic events (atrial fibrillation and premature beats) as supplemental information to its sleep information.

The performance testing demonstrates that the WP200U is substantially equivalent to its predicates and does not raise different questions of safety or effectiveness.

Summary

Based on the performance testing, including the electrical safety, electromagnetic testing, clinical study, and software verification and validation, Itamar Medical Ltd. concludes that the WP200U System is substantially equivalent to its predicates and does not raise any new or different concerns about safety or effectiveness.