September 5, 2025

Itamar Medical Ltd.
% John Smith
Partner
Hogan Lovells US LLP
555 13 St. NW
Washington, District of Columbia 20004

Re: K250460
Trade/Device Name: WatchPAT400 (WP400)
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: Class II
Product Code: MNR
Dated: July 31, 2025
Received: July 31, 2025

Dear John Smith:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Anesthesia,
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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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250460

Device Name
WatchPAT400 (WP400)

Indications for Use *(Describe)*
The WatchPAT400 (WP400) is a non-invasive home care device for use with patients suspected to have sleep related breathing disorders. The device is a diagnostic aid for the detection of sleep related breathing disorders, sleep staging (REM Sleep, Light Sleep, Deep Sleep and Wake), snoring level and body position. The WP400 generates a peripheral arterial tonometry ("PAT"), Respiratory Disturbance Index ("pRDI"), Apnea-Hypopnea index ("pAHI"), Central Apnea-Hypopnea index ("pAHIc"), sleep staging identification (pSTAGES) and optional snoring level and body position discrete states from an external integrated snoring and body position sensor. The device's pSTAGES and snoring level and body position provide supplemental information to its pRDI/pAHI/pAHIc. The device'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: September 2nd 2025

Trade Name: WatchPAT400 (WP400)

Common or Usual Name: Ventilatory Effort Recorder

Classification Name: Breathing Frequency Monitor

Medical Specialty: Anesthesiology

Product Code: MNR

Device Class: Class II

Regulation Number: 868.2375

Panel: Anesthesiology

Primary Predicate Device: WatchPAT ONE (WP1)
Itamar Medical Ltd, K223675; product code MNR

Reference Device: WatchPAT300 (WP300)
Itamar Medical Ltd, K222331; product code MNR

Indications for Use

The WatchPAT400 (WP400) is a non-invasive home care device for use with patients suspected to have sleep related breathing disorders. The device is a diagnostic aid for the detection of sleep related breathing disorders, sleep staging (REM Sleep, Light Sleep, Deep Sleep and Wake), snoring level and body position. The WP400 generates a peripheral arterial tonometry ("PAT") signal, Respiratory Disturbance Index ("pRDI"), Apnea-Hypopnea index ("pAHI"), Central Apnea-Hypopnea index ("pAHIc"), sleep staging identification (pSTAGES) and optional snoring level and body position discrete states from an external integrated snoring and body position sensor. The device's pSTAGES and snoring level and body position provide supplemental information to its pRDI/pAHI/pAHIc. The device'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 WP400 is a ventilatory effort recorder that utilizes PAT technology. The controller part of the device is worn on the wrist and records the PAT signal and arterial blood oxygen saturation levels by a finger-mounted probe based on an optical plethysmographic method. An actigraph, embedded in the wrist worn controller unit, records wrist motion that is used to determine periods of sleep vs wake. A chest sensor is attached to the patient's chest right under the sternal notch for measuring snoring level, body position states and chest movements. The device is battery powered and connects via Bluetooth to a mobile application.
The WP400 is a re-usable device, with sensors common with the WP300 and wireless connectivity identical to the WP1. With the same core technology, signal acquisition, and signal processing identical across all three WatchPAT devices, the WP400 is a combination of its predecessors: device housing leveraged from the WP300 for its re-usable nature, combined with the ability for wireless communication leveraged from the WP1. Signals recording, processing, and analysis has not changed from the predicate devices.

Substantial Equivalence

The WP400 has the same intended use and indications, with the same principles of operation as the predicates WP1 and reference device WP300. All are intended for use with patients suspected to have sleep related breathing disorders. The minor differences do not raise different questions of safety or effectiveness. Based on the comparison of intended use/indications for use, technological characteristics and testing, the WP400 can be found substantially equivalent to the predicate WP1.

	Subject Device: WP400	Primary Predicate Device: WP1 (K223675)	Reference Device: WP300 (K222331)	Comparison
Intended Use	The WatchPAT400 (WP400) is a non-invasive home care device for use with patients suspected to have sleep related breathing disorders. The device is a diagnostic aid for the detection of sleep related breathing disorders, sleep staging (REM Sleep, Light Sleep, Deep Sleep and Wake), snoring level and body position. The WP400 generates a peripheral arterial tonometry ("PAT") signal , Respiratory Disturbance Index ("pRDI"), Apnea-Hypopnea index ("pAHI"), Central Apnea-Hypopnea index ("pAHIc"), sleep staging identification (pSTAGES) and optional snoring level and body position discrete states from an external integrated snoring and body position sensor. The device's pSTAGES and snoring level and body position provide supplemental information to its pRDI/pAHI/pAHIc. The device'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 WPONE device is a non-invasive home care device for use with patients suspected to have sleep related breathing disorders. The WPONE 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 WPONE 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 WPONE's pSTAGES and snoring level and body position provide supplemental information to its pRDI/pAHI/pAHIc. The WPONE'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 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	Identical
User Population	Adult and adolescence (from age 12)	Adult and adolescence (from age 12)	Adult and adolescence (from age 12)	Identical
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	Identical
Intended Use Environment	Home Use	Home Use	Home Use	Identical

Input Finger (uPAT) Probe	Designed to use Itamar proprietary finger probe only to measure PAT and oximetry signals	Designed to use Itamar proprietary finger probe only to measure PAT and oximetry signals	Designed to use Itamar proprietary finer probe only to measure PAT and oximetry signals	Identical
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 • Arrhythmia flagging	• Respiratory Indices (pRDI, pAHI, pAHIc) • Sleep stages (REM, light, deep, and wake) • Snoring level • Body position discrete states • Heart Rate statistics • Oximetry Statistics • Arrhythmia flagging	• Respiratory Indices (pRDI, pAHI, pAHIc) • Sleep stages (REM, light, deep, and wake) • Snoring level • Body position discrete states • Heart Rate statistics • Oximetry Statistics • Arrhythmia flagging	Identical
HW Components	• uPAT finger probe (measures PAT and Oximetry) • actigraph (determines periods of sleep/wake) • Controller • Microphone • Accelerometer • Chest sensor (measures Respiratory Effort, Snoring level, and Body Position)	• uPAT finger probe (measures PAT and Oximetry) • actigraph (determines periods of sleep/wake) • Controller • Microphone • Accelerometer • Chest sensor (measures Respiratory Effort, Snoring level, and Body Position)	• uPAT finger probe (measures PAT and Oximetry) • actigraph (determines periods of sleep/wake) • Controller • Microphone • Accelerometer • Chest sensor (measures Respiratory Effort, Snoring level, and Body Position) • External Tamper-Proof Bracelet (optional)	Identical to WP1; similar to WP300 Tamper Proof Bracelet option of the WP300 is not available for the subject WP400.
Materials of wrist worn device	Re-usable device: • Wrist strap • Plastic Enclosure • Push Button	Disposable device: • Wrist strap • Plastic Enclosure	Re-usable device: • Wrist strap • Plastic Enclosure • Push Button	Identical to WP300
Sensors Placement	Wrist, finger and chest	Wrist, finger and chest	Wrist, finger and chest	Identical
Patient Management SW	zzzPAT/WP interface	zzzPAT/WP interface	zzzPAT/WP interface	Identical
Mobile Application	WatchPAT app for Android and iOS	WatchPAT app for Android and iOS	None	Similar to WP1 (minor differences exist in app instructions for turning on the device via push button (as opposed to battery insertion in the WP1) and returning of the WP400 to the clinic at the end of the test (as opposed to disposal of the WP1))

Power Supply	One OTS 1.5V Alkaline AAA battery	One OTS 1.5V Alkaline AAA battery	One OTS 1.5V Alkaline AAA battery OR One re-chargeable AAA 1.2V Nickel-metal hydride battery rechargeable (NiMH) battery	Identical to WP1; similar to WP300
Data Collection and transfer	• Sensors connect directly to main device. • Study data is wirelessly transferred (Bluetooth) from main device to mobile phone and from the mobile phone to cloud storage (WiFi/cellular) until downloaded by analysis SW	• Sensors connect directly to main device. • Study data is wirelessly transferred (Bluetooth) from main device to mobile phone and from the mobile phone to cloud storage (WiFi/cellular) until downloaded by analysis SW	• Sensors connect directly to main device. • Study data is stored on the main device and then uploaded via USB cable upon return of the device.	Identical to WP1; similar to the WP300
User Interface Display/ Indicators	• Main device LED • Push button • Mobile app	• Main device LED • Mobile app	• Main device OLED screen • 3 push buttons	Similar;
Principles of Operation	First, HCP registers a device to a specific patient. Second, the patient turns ON the device and follows the on-screen instructions on the mobile app to start the sleep study. Once recording has started, the sleep study data is transmitted in real time to a dedicated cloud storage location. Lastly, the HCP receives a notification that the sleep study is ready. The Patient Management SW analyzes the sleep study, allows reviewing of the signals, and generates the sleep report.	First, HCP registers a device to a specific patient. Second, the patient turns ON the device and follows the on-screen instructions on the mobile app to start the sleep study. Once recording has started, the sleep study data is transmitted in real time to a dedicated cloud storage location. Lastly, the HCP receives a notification that the sleep study is ready. The Patient Management SW analyzes the sleep study, allows reviewing of the signals, and generates the sleep report.	First, HCP registers a device to a specific patient. Second, the patient turns ON the device to start the sleep study. Once recording has started, the sleep study data is recorded to the device's on board memory. Lastly, the patient brings the device back to the HCP to download the data from the device. The Patient Management SW analyzes the sleep study, allows reviewing of the signals, and generates the sleep report.	Identical to WP1, similar to WP300.

Performance Data

The following tests were performed for the subject WP400:

1. Electrical safety, electrical safety for home use, and electromagnetic compatibility testing were conducted according to:
    - IEC 60601-1:2005, AMD1:2012, AMD2: 2020 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance,
    - IEC 60601-1-11:2015, AMD1:2020 - 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,

- IEC 60601-1-2:2014, AMD1:2020 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

The device met all acceptance criteria set forth in the standards.

2. The WP400 was tested to ensure that the device complies with the Federal Communications Commission (FCC) rules.
3. Content of Premarket Submissions for Device Software Functions Guidance Document. Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions Guidance Document. The Software Level of Concern was found to be Basic.
4. Although the hardware (e.g., sensors) and algorithms of WatchPAT400 are identical to the predicate (WatchPAT 300), a new clinical study was conducted to revalidate the SpO2 performance across varying skin tones. The clinical testing compared the SpO2 accuracy of the WatchPAT400 to arterial blood samples assessed by CO-Oximetry during non-motion conditions over the range of 70-100% SaO2. The study was conducted in accordance with ISO80601-2 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 ELEMENT Laboratories and included twenty-four healthy adult volunteer subjects. The participants had varying skin tones, assessed via Monk Skin Tone (MST) scale and Individual Topology Angle (ITA) measurements. The results of the study indicate SpO2 accuracy performance of the WatchPAT pass with an ARMS of 2.0% with upper 95% confidence intervals of 2.08%. Non- disparate performance was confirmed.

Conclusion

Based on the comprehensive comparison and performance testing presented in this 510(k) submission, the WatchPAT400 (WP400) is substantially equivalent to its predicate device, the WatchPAT ONE (K223675), as it shares identical intended use, core PAT technology, sensor components, signal processing algorithms, and clinical outputs. Minor differences in housing design and connectivity have been previously cleared in the respective reference device (K222331 – WatchPAT300). The performance testing demonstrates that the WP400 meets all established safety and performance criteria, and the identified differences do not raise new questions of safety or effectiveness, therefore supporting a determination of substantial equivalence.