July 31, 2026

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

Re: K254042
Trade/Device Name: WatchPAT SW
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: Class II
Product Code: MNR
Dated: July 2, 2026
Received: July 2, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

Binoy J. Mathews -S

Digitally signed by Binoy J. Mathews -S
Date: 2026.07.31 16:58:11 -04'00'

For
James J. Lee, Ph.D.
Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K254042

Device Name
WatchPAT SW

Indications for Use *(Describe)*
The WatchPAT SW analyzes data recorded by WatchPAT devices (WP300, WP1, WP400) and automatically generates respiratory indices, sleep stages, snoring level, and body position. WatchPAT SW is intended for use under the direction of a healthcare professional to aid in the diagnosis of obstructive and central sleep related breathing disorders.
Central indices are indicated for use in patients 17 years and older. All other outputs 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
K254042

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Date Prepared: July 31, 2026

Trade Name: WatchPAT SW

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: Watch-PAT 400 ("WP400") (Itamar Medical Ltd), cleared under K250460; product code MNR

Reference Device: DeepRESP, NOX Medical, K252330

Purpose of the 510(k) notice

ZOLL Itamar is introducing an update to the WatchPAT Software algorithm used for analysis of signals recorded from WatchPAT devices. The WatchPAT devices themselves remain unchanged - the current submission focuses on software modifications only (algorithm updates and new outputs). In the predicate device WP400, the WatchPAT SW (zzzPAT/WP Interface) was submitted as part of the WatchPAT device system.

Indications for Use

The WatchPAT SW analyzes data recorded by WatchPAT devices (WP300, WP1, WP400) and automatically generates respiratory indices, sleep stages, snoring level, and body position. WatchPAT SW is intended for use under the direction of a healthcare professional to aid in the diagnosis of obstructive and central sleep related breathing disorders.

Central indices are indicated for use in patients 17 years and older. All other outputs are indicated for 12 years and older.

Device Description

Similar to the WP Software in the WP400 predicate, the function of the WatchPAT SW is to register the device for a new study, download the recorded study data, view and analyze the data, and provide sleep reports with automatic analysis outputs for the HCP. The Sleep Reports generated by the updated WatchPAT SW are the same as the predicate, with the addition of two new outputs. Use of the WatchPAT SW with all three WatchPAT devices provides similar output information and sleep reports.

Technological Characteristics

The principles of operation are the same between the updated WatchPAT SW and the predicate SW which was submitted with the WP400 (K250460). The input signals to the SW are the same as in the predicate device. The main differences are that there are two main algorithms modified in this submission, (1) sleep staging and (2) event detection (including two new outputs, Apnea Index and Arousal Index).

The WatchPAT SW provides the following outputs, same as the predicate device:

(1) Respiratory Disturbance Index "RDI"
(2) Apnea-Hypopnea index "AHI"
(3) Central Apnea-Hypopnea index "AHIc"
(4) Sleep stages
(5) Body position
(6) Snoring level (in decibels)
(7) Cheyne Stokes Respiration pattern "%CSR", and
(8) Atrial Fibrillation and Premature Beats (flagging only, as additional information to the sleep report).

Out of the above outputs, RDI, AHI, AHIc, and sleep stages algorithms are updated in this submission. Body Position, Snoring level, %CSR and Arrhythmia detection feature are unchanged.

In addition, WatchPAT SW provides the following new outputs:

(1) Apnea Index "AI" and
(2) Arousal Index "ArI".

The reference device DeepRESP SW K252330 is used to support evaluation of specific new outputs. DeepRESP SW (K252330) provides comparable outputs, including Apnea Index, Arousal

Index, and 5-level Sleep Staging including N1 and N2.

The clinical performance data submitted supports the inclusion of the updated and new outputs to WatchPAT SW.

SW Design and Development

The updated WatchPAT SW is a Machine Learning Medical Device (MLMD) that does not perform continuous learning; for a given set of inputs, there will always be the same output. The input signals to the updated WatchPAT SW are the same as in the predicate device. The updated SW uses ML technologies (including several Neural Network models and other classifiers) to improve Events Detection and Sleep Stages algorithms. The Classifiers, combining Machine Learning and heuristics were used in the updated SW to achieve enhanced performance.

Training of the models was performed using over 900 WatchPAT night studies collected as part of clinical trials in which WatchPAT recordings were obtained simultaneously with in-laboratory polysomnography (PSG) in sleep laboratory settings. The data was collected across geographically diverse sites, including U.S. and non-U.S. centers. Training data included patients referred for sleep studies due to suspected sleep disorders and/or patients with cardiovascular comorbidities justifying referral for sleep assessment. The dataset includes a wide age range, a broad BMI distribution spanning underweight through morbidly obese and representation of both sexes consistent with proportions reported in the literature for sleep laboratory referred populations.

The PSG data was manually scored by experienced and qualified sleep lab technicians/physicians and served as the reference for the training process (supervised learning).

Principles of Operation

The principles of operation are identical between the subject WatchPAT SW and the predicate SW which was submitted with the WP400 (K250460). First, the HCP registers the device to a specific patient. Once the patient performs the sleep study in their home, the data is either automatically uploaded via the cloud for the wireless configurations (WP400 and WP1) or manually uploaded to the WatchPAT SW via USB cable for WP300. Within WatchPAT SW, the HCP can then view the signals with automatic analysis, manually edit, and generate the sleep report.

Performance and Safety Data

A series of safety and performance testing similar to the predicates were performed. These tests include non-clinical and clinical performance testing as listed below:

Non-Clinical Performance

- The device was designed and tested under the following standards and guidelines:
    - EN ISO 14971 Third Edition 2019-12 Medical devices - Application of risk management to medical devices
    - IEC 62304 Edition 1.1 2015-06 Medical device software - Software life cycle processes
    - Content of Premarket Submissions for Device Software Functions – FDA guidance issued June 2023.
- Software verification and validation testing was conducted to verify that the SW performs

according to its specifications as described in the Software Requirements Specifications (SRS). The Software Test Description (STD) demonstrates that the WatchPAT SW performs according to its specifications.

- The following FDA guidance were conformed to:
    - Content of Premarket Submissions for Device Software Functions: June 2023
    - Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions: September 2023

Clinical Performance

Clinical testing was conducted to evaluate the performance of the WatchPAT device using the updated SW to aid in the diagnosis of sleep disordered breathing and sleep staging against polysomnography (PSG), considered the "gold standard". The manual scoring of the PSG, in accordance with the AASM sleep scoring guidelines, was performed for each recording by two independent sleep scorers. A total of 246 patients were included in the performance validation for device outputs.

Results: Across all evaluated outputs, the WatchPAT SW met the performance goals. The WatchPAT SW demonstrated diagnostic accuracy and agreement relative to the gold standard PSG scorers including AHI, RDI, AHIc and Sleep Stages. The results for new indices introduced, apnea index (AI) and arousal index (ArI), indicated their suitability for clinical use.

Output	Results	
AHI	AHI3% Sensitivity 0.91 (TH≥15) Specificity 0.93 (TH≥15) Cohen's Kappa κ=0.80 (TH≥15) ICC 0.95	AHI4% Sensitivity 0.92 (TH≥15) Specificity 0.96 (TH≥15) Cohen's Kappa κ=0.88 (TH≥15) ICC 0.96
RDI	RDI3% Sensitivity 0.87 (TH≥15) Specificity 0.92 (TH≥15)	RDI4% Sensitivity 0.90 (TH≥15) Specificity 0.93 (TH≥15)
AHIc	AHIc3% Sensitivity 0.88 (TH≥10) Specificity 0.94 (TH≥10)	AHIc4% Sensitivity 0.93 (TH≥10) Specificity 0.96 (TH≥10)
AI	Sensitivity 0.79 (TH≥5) Specificity 0.97 (TH≥5)	
ArI	Sensitivity 0.86 (TH≥30) Specificity 0.82 (TH≥30)	
Sleep Stages	Cohen's Kappa 5 levels κ=0.65 Sleep/Wake κ=0.77 REM/non-REM κ=0.72	

Results presented for indices (AHI, AHIc, AI, ArI) are the Updated SW comparison to the average of the two PSG scorers. For RDI, a single scorer was used. Results for Sleep Stages are presented as comparison to consensus of scorers.

Performance Summary

Overall, the updated WatchPAT SW met all the objective performance goals. The results demonstrated substantially equivalent performance with an adequate degree of accuracy and agreement between the Updated WatchPAT SW and the 2 scorers for all outputs.

Substantial Equivalence

The table below compares the technological characteristics of the Updated WatchPAT SW to the predicate SW submitted as part of the WatchPAT400 device.

Table 1. Substantial Equivalence Comparison table

Properties	Subject Device: **WatchPAT SW**	Predicate Device: K250460 **SW as part of WP400**	Reference Device: K252330 **DeepRESP** **For specific technical characteristics**	Comparison
Intended Use/Indications for use	The WatchPAT SW analyzes data recorded by WatchPAT devices (WP300, WP1, WP400) and automatically generates respiratory indices, sleep stages, snoring level, and body position. WatchPAT SW is intended for use under the direction of a healthcare	Intended use of the WP400 device: The WatchPAT device is a non-invasive home care device for use with patients suspected to have sleep related breathing disorders. The WatchPAT is a diagnostic aid for the detection of sleep related breathing disorders, sleep	N/A	Similar. The intended use is simplified for clarity relative to the WP400 device (predicate).

	professional to aid in the diagnosis of obstructive and central sleep related breathing disorders. Central indices are indicated for use in patients 17 years and older. All other outputs are indicated for 12 years and older.	staging (Rapid Eye Movement (REM) Sleep, Light Sleep, Deep Sleep and Wake), snoring level and body position. The WatchPAT generates a peripheral arterial tonometry ("PAT") Respiratory Disturbance Index ("PRDI"), Apnea-Hypopnea index ("PAHI"), Central ApneaHypopnea 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 WatchPAT's PSTAGES and snoring level and body position provide supplemental information to its PRDI/PAHI/PAHIc. The WatchPAT'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		
Patient Population	12 years and above	12 years and above	N/A	Same.
Environment of Use	Professional Use setting office/clinic/hospital	zzzPAT/WPInterface SW: Professional Use setting office/clinic/hospital	N/A	Same.
Data Access	For WP1 and WP400 (wireless configurations) download data from cloud server. For WP300 (wired configuration) download data from device wired USB connection	For WP1 and WP400 (wireless configurations) download data from cloud server. For WP300 (wired configuration) download data from device wired USB connection	N/A	Same.

Principle of operation	First, the HCP registers the device to a specific patient. Once the patient performs the sleep study in their home, the data is either automatically uploaded to the cloud for the wireless configurations (WP400 and WP1) or manually uploaded to the WatchPAT Analysis SW via USB cable for WP300. Within the WatchPAT Analysis SW the HCP downloads the sleep study data, and can then view the signals, run the automatic analysis, manually edit the signals, and generate the sleep report.	First, the HCP registers the device to a specific patient. Once the patient performs the sleep study in their home, the data is either automatically uploaded to the cloud for the wireless configurations (WP400 and WP1) or manually uploaded to the WatchPAT Analysis SW via USB cable for WP300. Within the WatchPAT Analysis SW the HCP downloads the sleep study data, and can then view the signals, run the automatic analysis, manually edit the signals, and generate the sleep report.	N/A	Same.
Compatible Input Devices	WatchPAT devices: WP300, WP1, WP400	WatchPAT devices: WP300, WP1, WP400	N/A	Same.
Input signals	PAT, Pulse rate, Oximetry, Actigraphy, Snoring, Body Position, Chest Movement	PAT, Pulse rate, Oximetry, Actigraphy, Snoring, Body Position, Chest Movement	N/A	Same.
Outputs	AHI, AHIc, %CSR, RDI, AI, ArI Snoring level Body position – 5 discrete states 5 Sleep Stages, N1 N2 N3 REM Wake AFIB, PB Oxygen Saturation Statistics	pAHI, pAHIc, %CSR, pRDI Snoring level Body position – 5 discrete states 4 Sleep Stages, Light Deep REM Wake AFIB, PB Oxygen Saturation Statistics	AHI, CAHI, All Apnea, Central Apnea, Obstructive Apnea, Hypopnea, Arousal Events, Desaturation, Sleep Stages (N1 N2 N3 REM Wake), Position	Similar to predicate. Apnea Index (AI), Arousal Index (ArI) and differentiation of "Light" sleep stage into N1 and N2 are similar to Reference device.
Main Performance Results	AHI (threshold = 15) Sensitivity 91% Specificity 93% AHIc (threshold = 10) Sensitivity 88% Specificity 94% Sleep Stages Cohen's Kappa 0.65 All apnea Sensitivity 0.79 (TH≥5) Specificity 0.97 (TH≥5) Arousal events Sensitivity 0.86 (TH≥30) Specificity 0.82 (TH≥30)	AHI (threshold = 15) Sensitivity 85% Specificity 88.2% AHIc (threshold = 10) Sensitivity 71.4% Specificity 98.6% Sleep Stages Cohen's Kappa 0.46	All apnea PPA%: 83.7 NPA%: 98.2 OPA%: 97.1 Arousal events PPA%: 62.1 NPA%: 89.1 OPA%: 81.5	Similar.
Editing functionality	Automatic analysis for all outputs, with capability to manually edit	Automatic analysis for all outputs, with capability to manually edit	N/A	Same.

Sleep Report	Comprises of Outputs generated, graphics, histograms, patient information	Comprises of Outputs generated, graphics, histograms, patient information	N/A	Similar. Only difference is adaptation to add the new indices and sleep stages.
Algorithmic Design	Non-continuous learning MLMD Deterministic	Non-continuous learning Deterministic	N/A	Similar. Subject WatchPAT SW utilizes modern ML technologies. Safety and effectiveness of algorithm has been verified and validated via non-clinical and clinical testing.
Cybersecurity	Encrypted HTTPS/TLS1.2 secure data transfer	Encrypted HTTPS/TLS1.2 secure data transfer	N/A	Same.

The subject device (WatchPAT SW) is submitted separately from previously cleared hardware, while the primary predicate K250460 is the complete WatchPAT 400 system. This software-only submission approach is justified by precedent (Reference device: K241960 DeepRESP SW cleared separately from NOX Sleep System hardware) and reflects the common software platform used across all WatchPAT hardware configurations with independent software lifecycle management.

Conclusion

The Updated WatchPAT SW has the same intended use and similar indications as the predicate SW (zzzPAT/WPInterface) submitted in K250460. Both are intended for use with patients suspected of having sleep related breathing disorders. The subject WatchPAT SW does not raise different questions of safety or effectiveness, as all new outputs are based on the same inputs that exist in the previous FDA-cleared products and use thereof under a diagnostic aid indication does not alter the clinical utility or risk of the device. Further, non-clinical and clinical performance testing were conducted, and all testing demonstrated substantially equivalent performance. Based on the comparison described above, the updated WatchPAT SW is found substantially equivalent to the predicate zzzPAT/WPInterface.