October 30, 2026

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

Re: K260648
Trade/Device Name: PolySense
Regulation Number: 21 CFR 882.1835
Regulation Name: Physiological Signal Amplifier
Regulatory Class: Class II
Product Code: GWL, DSH
Dated: September 30, 2026
Received: September 30, 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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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

Office of Industry and Consumer Education (OICE) to ask a question about a specific regulatory topic. See the OICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-office-industry-and-consumer-education-oice) for more information or contact OICE by email (AskOICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

KEVIN H. KHUU -S

Digitally signed by KEVIN H. KHUU -S
Date: 2026.10.30 10:52:19 -04'00'

for
Patrick Antowiak
Acting Assistant Director
DHT5A: Division of Neurosurgical, Neurointerventional, and Neurodiagnostic Devices
OHT5: Office of Neurological and Physical Medicine 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)*
K260648

Device Name
PolySense

Indications for Use *(Describe)*
PolySense is a prescription-use physiological data recorder intended to collect, amplify, and transmit recorded data acquired from multiple physiological channels: EEG, EOG, EMG, ECG, and accelerometry to aid in the diagnosis of sleep disorders. PolySense is an accessory to the WatchPAT cleared in K250460, indicated for patients suspected of having sleep disorders for ages 18 and older in a home or clinical environment. PolySense does not provide any automated analysis. Recorded signals can be manually scored by the HCP using WatchPAT Software (SW).

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Traditional 510(k) Summary - K260648

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Date Prepared: October 30th 2026

Trade Name: PolySense

Common or Usual Name: Physiological Signal Amplifier

Classification Name and Number: Physiological Signal Amplifier; 21 CFR 882.1835

Product Code: GWL

Secondary Product Code: DSH - Medical magnetic tape recorder – 21 CFR 870.2800

Device Class: Class II

Predicate Device: DreamClear (REMware), K240646; product code GWL

Reference Device: Zio Monitor (iRhythm Technologies, Inc.), K202359; product code DSH

Intended Use

PolySense is a prescription-use physiological data recorder intended to collect, amplify, and transmit recorded data acquired from multiple physiological channels: EEG, EOG, EMG, ECG, and accelerometry to aid in the diagnosis of sleep disorders. PolySense is an accessory to the WatchPAT cleared in K250460, indicated for patients suspected of having sleep disorders for ages 18 and older in a home or clinical environment. PolySense does not provide any automated analysis. Recorded signals can be manually scored by the HCP using WatchPAT Software (SW).

Device Description

The PolySense device is a physiological data recorder that records and transmits Electroencephalography

(EEG), Electrooculography (EOG), Electromyography (EMG), Electrocardiography (ECG), and accelerometry from sensors placed in various locations on the patient's body. The PolySense product is composed of 2 main components:

(1) PolySense Module – a reusable electronic component that is capable of acquiring the data and communicating with the mobile application over Bluetooth, and

(2) PolySense Patch – a disposable electronic circuit embedded on a wearable adhesive patch. There are 3 types of patches – Head patch, Cardiac patch, Leg patch. Each patch connects to a reusable electronic module, identical for all patches.

The PolySense accessory transmits recorded signals via Bluetooth to the WatchPAT mobile application which then transmits the signals wirelessly to the cloud.

The WatchPAT Software (SW) retrieves the sleep study data from the cloud. The channels provided by PolySense enable the Health Care Provider (HCP) to view and manually score EEG, EOG, EMG, ECG, and movements. Events are identified manually and are then summarized to the sleep report.

Substantial Equivalence

PolySense has similar indications for use as the predicate DreamClear. Both are physiological data recorders intended to record, collect, amplify, and transmit physiological signals (EEG, EOG, EMG, and limb movement) in a home or healthcare environment to aid in the diagnosis of sleep disorders. The additional ECG signal acquired by PolySense that is not present in the intended use of the predicate is similar in functionality to the reference device, Zio Monitor. PolySense and DreamClear are both prescription use and provided non-sterile. PolySense has similar technological characteristics to the predicate device DreamClear, with differences that are supported by the reference device, Zio Monitor that do not raise different questions of safety or efficacy. Performance testing demonstrated clear evidence in support of the device's safety and effectiveness. Based on evaluation of the intended use, technological characteristics, and performance testing, the PolySense device is substantially equivalent to the predicate DreamClear.

Properties	Subject Device: K260648 PolySense	Predicate Device: DreamClear (K240646)	Reference Device: Zio Monitor (K202359)	Comments
Indications for Use (IFU) Statement	PolySense is a prescription-use physiological data recorder intended to collect, amplify, and transmit recorded data acquired from multiple physiological channels: EEG, EOG, EMG, ECG, and accelerometry, to aid in the diagnosis of sleep disorders. PolySense is an accessory to the WatchPAT cleared in K250460, indicated for patients suspected of having sleep disorders for ages 18 and older in a home or clinical environment. PolySense does not provide any automated analysis. Recorded signals can be manually scored by the HCP using WatchPAT Software (SW).	DreamClear is intended for use on both adults and children to collect, amplify, and transmit physiological signals acquired from a patient, including electroencephalogram (EEG), electrooculography (EOG), limb movement, respiration effort, air pressure, and peripheral oxygen saturation (SpO2). DreamClear is intended for use on the order of a physician and is non-sterile. While primarily intended for use with dedicated polysomnography software to aid in the diagnosis of sleep disorders, DreamClear may be used to amplify physiological signals for any medical diagnostic procedure that does not involve: use alone as an apnea monitor or as a critical component in an apnea monitoring system; or use alone as a life support device or as a critical component of a life support system.	The Zio Monitor is a prescription-only, single-patient-use, ECG monitor that continuously records data for up to 14 days. It is indicated for use on patients who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, lightheadedness, pre-syncope, syncope, fatigue or anxiety.	Similar to predicate DreamClear. PolySense Indications are a subset of DreamClear, for collecting, amplifying, and transmitting EEG, EOG, EMG signals to aid in the diagnosis of sleep disorders. The difference in additional recording of ECG signal is supported by the reference device Zio Monitor.
Product Codes	GWL (DSH)	GWL (MNR, DQA)	DSH	Primary product code and regulation are the same
Target Population	Adults (18 and above)	Adults and children	Adults (18 and above)	Similar
Environment for Use	Home or Healthcare facility	Home or Healthcare facility	Home	Same as predicate
Usage type	Reusable electronic module Single use patch	Reusable electronics module	Single use patch	Reusable electronic module like predicate Patch Form factor like reference device
Sold Sterile or Non-Sterile	Nonsterile	Nonsterile	Nonsterile	Same
Data Transfer and storage	Bluetooth to mobile app	Bluetooth to mobile app	Data stored on device	Similar to predicate
Recording Time	Overnight sleep study (10 hours)	Overnight sleep study	14 Days	Similar to Predicate

Properties	Subject Device: K260648 PolySense	Predicate Device: DreamClear (K240646)	Reference Device: Zio Monitor (K202359)	Comments

Possible Channels	• EEG
	• EOG
	• EMG
	• ECG
	• Movement (accelerometer)
		• EEG
		• EOG
		• EMG (limb movement)
		• Nasal airflow
		• Snore (Microphone),
		• Respiratory Thoracic Effort,
		• Body Position
		• Pulse Oximetry, including:
		  ○ SpO2
		  ○ Pulse Rate
			ECG	Subset of predicate
				
				ECG function referenced from Zio Monitor

Form Factor	Adhesive Patch	Electronic box with off the shelf electrodes	Adhesive Patch	Similar to Reference Device

Performance Data

A series of safety and performance testing similar to the predicates were performed. These tests include the following:

1. Electrical Safety:
   - ANSI/AAMI ES60601-1:2005/(R) 2012 and A1:2012, C1:2009/(R) 2012 and A2:2010/(R) 2012 [Including Amendment 2 (2021)] :Medical electrical equipment: Part 1: General requirements for basic safety and essential performance
     - PolySense device was tested and demonstrated to be safe in case of External Defibrillation (8.5.5.2 compliant).
   - IEC 60601-1-11:2015/AMD1:2020 Medical electrical equipment: Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: home healthcare environment
   - IEC 60601-2-47:2012 Medical electrical equipment – Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographs
   - ISO/IEC 80601-2-26:2020, Particular requirements for the basic safety and essential performance of electroencephalographs
   - IEC 60601-2-40:2024, Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment
   - ANSI/AAMI EC12:2020 Disposable ECG Electrodes

2. Electromagnetic Compatibility:
   - Safety: 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
   - Performance: IEC TS 60601-4-2:2024 Medical electrical equipment – Part 4-2: Guidance and Interpretation – Electromagnetic immunity – performance of medical electrical equipment and

medical electrical systems

3. Biocompatibility Testing was conducted in accordance with Biological evaluation of medical devices - Part 1: Evaluation and testing ISO10993-1
   - Cytotoxicity ISO10993-5:2009
   - Sensitization ISO10993-10:2021
   - Irritation ISO10993-23:2021

4. Usability:
   - IEC 60601-1-6:2010/AMD1:2013/AMD2:2020, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
   - Human factors testing in accordance with the FDA guidance document, "Applying Human Factors and Usability Engineering to Medical Devices". Additionally, qualitative evaluation was performed on the signals recorded from the usability testing.

5. Software verification and validation testing were conducted to verify that the device performs according to its specifications as described in the Software Requirements Specifications (SRS). The Software Test Description (STD) for the PolySense, including the FW, WatchPAT SW and the mobile application demonstrate that the PolySense performs according to its specifications.

6. PolySense was tested to ensure that the device complies with the Federal Communications Commission (FCC) rules.
7. Shelf-Life testing was performed for the PolySense Adhesive Patch in accordance with FDA Guidance: "Cutaneous Electrodes for Recording Purposes – Performance Criteria for Safety and Performance Based Pathway".

The Safety and Performance testing all passed successfully, demonstrating the substantial equivalence of the PolySense to the predicate.

Conclusion

PolySense has the same intended use as the predicate device DreamClear. Both devices are intended for use with patients suspected of having sleep disorders. Differences in technological characteristics do not raise different questions of safety or effectiveness and are accounted for with adequate performance testing and a reference device, Zio Monitor. Testing passed successfully, demonstrating substantial equivalence. Based on a comparison of the intended use, technological characteristics, and performance testing, the PolySense device is substantially equivalent to the predicate DreamClear.