January 16, 2025

Inmedix, Inc.
% Michael Daniel
Consultant
Daniel & Daniel Consulting, LLC
P.O. Box 129
Minden, Nevada 89423

Re: K241217
Trade/Device Name: CloudHRV™ System (100-01-001)
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: December 20, 2024
Received: December 20, 2024

Dear Michael Daniel:

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,

Jennifer W. Shih -S

Jennifer Kozen
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics, and Monitoring Devices
Office of Cardiovascular 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)*
K241217

Device Name
CloudHRV™ System

Indications for Use *(Describe)*
The Inmedix® CloudHRV™ System is intended to acquire, display, and record electrocardiographic (ECG) information to measure heart rate variability (HRV) in adult patients (age 22 or above) with normal sinus rhythm and resting heart rate within 40 – 110 bpm. These measurements are not intended for any specific clinical diagnosis. The clinical significance of HRV must be determined by the physician.

Assessment is indicated for patients in a healthcare facility including a physician office or a hospital outpatient clinic where the patient is able to remain supine and still. The CloudHRV™ System is not indicated for use in a surgical suite or during transport.

Normal sinus rhythm is determined by the physician. The ECG is not intended to be used to diagnose or monitor cardiovascular conditions. The device does not provide assessments of cardiovascular abnormalities/arrhythmias.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Premarket Notification 510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number: K241217

Applicant Information:

Date Prepared: April 29, 2024

Name: Andrew Holman MD

Address: Inmedix, Inc.

17837 First Avenue South, #6,

Normandy Park, WA 98148, USA

Contact Person: Michael A. Daniel

Email: madaniel@clinregconsult.com

Device Information:

Device Trade Name: CloudHRV™ System

Common Name: CloudHRV™ System

Classification Name(s): Electrocardiograph

Product Code/ Regulation: DPS / 870.2340

Classification: 2

Predicate Device:

ANSiscope™ ECG Monitoring System (K071168)

Subject Device Description

The Inmedix® CloudHRV™ System acquires approximately 5 minutes of 3-lead electrocardiographic (ECG) data from a patient lying supine and at rest to measure heart rate variability (HRV). The raw cardiac electrical signals are detected using four standard ECG electrodes applied to the wrists and ankles of the patient and a custom 4-lead wire (one reference) ECG cable assembly.

The ECG data collected from the patient are transmitted to a cloud-based service hosted by Inmedix, where proprietary mathematical algorithms calculate HRV. The CloudHRV™ System outputs are used as an aid by clinicians who are accustomed to evaluating HRV as a part of their overall medical assessment.

Subject Device Intended Use

The Inmedix® CloudHRV™ System is intended to acquire, display, and record electrocardiographic (ECG) information to measure heart rate variability (HRV). These measurements are not intended for any specific clinical diagnosis. The clinical significance of HRV must be determined by the physician.

Subject Device Indications for Use

The Inmedix® CloudHRV™ System is intended to acquire, display, and record electrocardiographic (ECG) information to measure heart rate variability (HRV) in adult patients (age 22 or above) with normal sinus rhythm and resting heart rate within 40 - 110 bpm. These measurements are not intended for any specific clinical diagnosis. The clinical significance of HRV must be determined by the physician.

Assessment is indicated for patients in a healthcare facility including a physician office or a hospital outpatient clinic where the patient is able to remain supine and still. The CloudHRV™ System is not indicated for use in a surgical suite or during transport.

Normal sinus rhythm is determined by the physician. The ECG is not intended to be used to diagnose or monitor cardiovascular conditions. The device does not provide assessments of cardiovascular abnormalities/arrhythmias.

Predicate Device and Subject Device Comparison

The table below compares the CloudHRV to the predicate device.

Table 1 - Comparison between subject and predicate device

Aspect	Predicate Device	Subject Device	Comparison
Device Name	ANSiscope™ ECG Monitoring System	CloudHRV™ System	N/A
510(k) Number	K071168	K241217	N/A
Manufacturer	DyAnsys, Inc.	Inmedix, Inc.	N/A
Product Code / Regulation	DPS / 870.2340	DPS / 870.2340	Same
Brief Description	The Portable ANSiscope™ is a device used for measuring heart rate variability (HRV). The device is designed to process raw ECG signals acquired from the patient in order to produce Heart Rate and other ancillary indices. The Portable ANSiscope™ includes an ECG Acquisition System that can digitize raw ECG signals, perform proprietary calculations from the HRV and then display the results utilizing a display unit.	The CloudHRV™ System is a device used for measuring heart rate variability (HRV). The device acquires ~5 minutes of 3-lead ECG data from a patient lying supine and at rest. ECG data is transmitted to a cloud-based service hosted by Inmedix, where proprietary mathematical algorithms calculate HRV and then display the results on the Tablet. The results are used as an aid by clinicians who are accustomed to evaluating HRV as a	Substantially Equivalent

Aspect	Predicate Device	Subject Device	Comparison
		part of their overall medical assessment.	
Intended Use	The DyAnsys, Inc. ANSiscope™ ECG Monitoring System and accessories, is intended to acquire, analyze, display and record electrocardiographic information and to measure-heart rate variability. These and other measurements are not intended for any specific clinical diagnosis. The clinical significance of HRV and other parameters must be determined by the physician.	The Inmedix® CloudHRV™ System is intended to acquire, display, and record electrocardiographic (ECG) information to measure heart rate variability (HRV). These measurements are not intended for any specific clinical diagnosis. The clinical significance of HRV must be determined by the physician.	Substantially Equivalent
Indications for Use	The DyAnsys, Inc. ANSiscope™ ECG Monitoring System and accessories, is intended to acquire, analyze, display and record electrocardiographic information and to measure-heart rate variability. These and other measurements are not intended for any specific clinical diagnosis. The clinical significance of HRV and other parameters must be determined by the physician.	The Inmedix® CloudHRV™ System is intended to acquire, display, and record electrocardiographic (ECG) information to measure heart rate variability (HRV) in adult patients (age 22 or above) with normal sinus rhythm and resting heart rate within 40 - 110 bpm. These measurements are not intended for any specific clinical diagnosis. The clinical significance of HRV must be determined by the physician. Assessment is indicated for patients in a healthcare facility including a physician office or a hospital outpatient clinic where the patient is able to remain supine and still. The CloudHRV™ System is not indicated for use in a surgical suite or during transport. Normal sinus rhythm is determined by the physician. The ECG is not intended to be used to diagnose or monitor cardiovascular conditions. The device does not provide assessments of cardiovascular abnormalities/arrhythmias.	Substantially Equivalent
Displayed Parameters - ECG related	• Real-time ECG waveform • Real-time heart rate • ECG lead selection	• Real-time ECG waveform during assessment	Substantially Equivalent

Aspect	Predicate Device	Subject Device	Comparison
		• Real-time heart rate during assessment • Static ECG waveform - post assessment • Static average heart rate - post assessment	
Displayed Parameters – HRV related	• Real-time sympathovagal balANS (from -50 to 50) • Real-time sympathetic ANSi index (from -50 to 50) • Real-time parasympathetic ANSi index (from -50 to 50) • Measurement of Dysfunction: Static balANS, Percent of dysfunction	• Statistical Time-Domain Indices: SDNN, SDSD, RMSSD • Geometric Time-Domain Indices: DRR, AMO, Baevsky Index • Frequency Domain Indices: High Frequency, Low Frequency, Total power, LF/HF ratio	Substantially Equivalent
Type of Analysis	Separation of sympathetic and parasympathetic components of the Autonomic Nervous System (ANS) by scale covariance approach Sympathetic response is real part of complex wave function Parasympathetic response is imaginary part of complex wave function	HRV indices calculated using ~5 minutes of RR interval series with signal normalized and artifacts removed.	Substantially Equivalent
Number of Electrodes	Three (3) for HRV One (1) for grounding Chest lead for ECG functionality	Three (3) for vectors I, II, III One (1) for grounding (right leg drive)	Substantially Equivalent
Electrode location	Chest lead, torso, right ankle.	Left and right wrists, left and right ankles	Substantially Equivalent
Measurement	The initial ANSindex reading is displayed after 60 R-R intervals (approx 1 minute) Subsequent readings are taken with every heartbeat The display is updated with every heartbeat	Records five (5) minutes of ECG to calculate all indices	Substantially Equivalent
Standard leads acquired	I, II, III, aVR, aVL, aVF, V1-6	I,II,III	Substantially Equivalent

Aspect	Predicate Device	Subject Device	Comparison
Digital sampling rate	200 samples/sec	500 samples/sec	Substantially Equivalent
DC offset capability	300 mV DC	280 mV DC	Substantially Equivalent
Sampling resolution	16 bit, bipolar	16 bit, bipolar	Same
Frequency response	0.5 Hz to 40 Hz	0.5 Hz to 113 Hz	Substantially Equivalent
Data Storage Capability	• USB memory keys (Thumb drives) can be used for data storage/backup • Also supports SCSI compatible USB mass storage devices • Data can be exported to a PC via a USB memory key	Patient Health Information and patient indices are stored in the secure Inmedix Cloud. Data can be made available as a PDF	Substantially Equivalent
Electrical Safety Classification	Class II - Type CF device as per IEC requirements	Class II - Type CF device as per IEC requirements	Same
AC adapter input	100-240 VAC, 50-60 Hz	100-240 VAC, 50-60 Hz	Same
AC adapter output	12 VDC, 2 Amps max	12 VDC, 2 Amps max	Same
Battery pack type	NiMH rechargeable battery	Lithium-ion	Substantially Equivalent

Testing Completed

Design verification testing included use of the following standards:

- IEC 60601-1: 2005+A1:2012+A2:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014+A1:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-2-25:2011/(R2016) Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs
- 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

- IEC 62366-1:2015, AMD1:2020 Medical devices — Part 1: Application of usability engineering to medical devices
- ANSI/AAMI EC57:2012 Testing and reporting performance results of cardiac rhythm and ST-segment measurement algorithms.
- ANSI/AAMI EC53:2013/(R2020) – ECG trunk cables and patient leadwires
- ASTM D4169-22 – Standard practice for performance testing of shipping containers and systems.
- IEC 62304:2006 +AMD1:2015 Medical device software - Software life-cycle processes

Adherance to the following FDA Guidance Documents:

- FDA Guidance - Content of Premarket Submissions for Device Software Functions. Issued June 14, 2023.
- FDA Guidance - Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions. Issued September 27, 2023.

Design validation testing included the following:

- Design Validation by Design Review against the Product Requirements (User and Stakeholder Requirements)
- Human Factors and Usability Engineering Report

The testing described in this 510(k) demonstrates that the design input requirements have been verified and all user requirements were validated.

Conclusion

Verification and validation activities were conducted to establish the performance and safety characteristics of the Inmedix CloudHRV™ System. The results of these activities demonstrate that the CloudHRV™ System is as safe and effective as compared to the predicate when used in accordance with its intended use, indications for use and labeling. The CloudHRV™ System has similar intended use and technical characteristics to the predicate device. Therefore, it is substantially equivalent to the predicate device and does not raise any new questions regarding safety or effectiveness as compared to the predicate.