June 17, 2025

VitalSigns Technology Co., Ltd.
Leon Chuang
Chief of Technology Officer
3F., No. 153, Ziqiang S. Rd., Zhubei City
Hsinchu County, 302042
Taiwan

Re: K243003
Trade/Device Name: VitalSigns 1-Lead Holter (VSH101)
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone electrocardiograph transmitter and receiver
Regulatory Class: Class II
Product Code: DXH
Dated: May 23, 2025
Received: May 23, 2025

Dear Leon Chuang:

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.

Submission Number *(if known)*

K243003

Device Name

VitalSigns 1-Lead Holter (VSH101)

Indications for Use *(Describe)*

The VSH101 is designed to record, transmit, and store single channel electrocardiogram (ECG) data via Bluetooth communication to compatible Bluetooth enabled devices. The device is intended for use by healthcare professionals, individuals with known or suspected cardiac conditions, and health-conscious users. The ECG data serves as a supplementary source of patient information and is not intended for automated analysis.

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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510(K) Summary

1. Submitter

510(K) Sponsor	VitalSigns Technology Co., Ltd
Address	3F., No. 153, Ziqiang S. Rd., Zhubei City, Hsinchu County 302042, Taiwan (R.O.C.)
Applicant	JIH-LIANG, JUANG
Contact Information	TEL: +886-3-6682091 Mail: jl_juang@vsigntek.com
Correspondent Person	JIH-LIANG, JUANG
Contact Information	TEL: +886-3-6682091 Mail: jl_juang@vsigntek.com
Date	2025/05/23

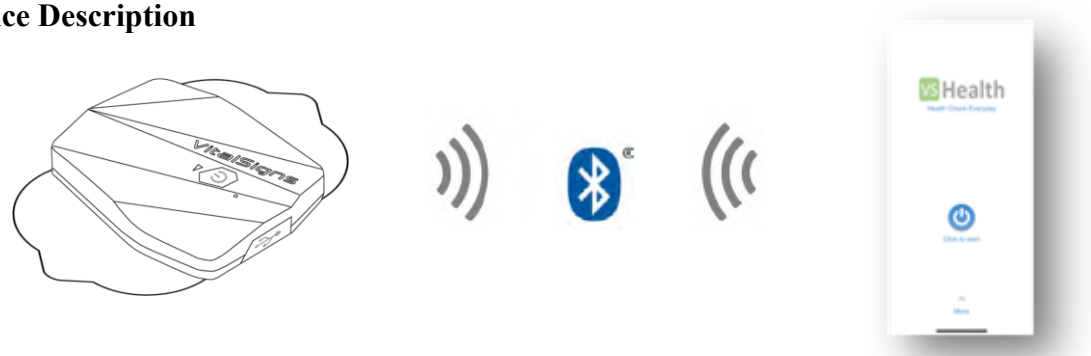
2. Subject device

Device Name	VitalSigns 1-Lead Holter
Regulation Name	Telephone electrocardiograph transmitter and receiver
Regulation Number	21 CFR870.2920
Product Code	DXH
510(k) review	Cardiovascular
Regulatory Class	Class II

3. Predicate device

Device Name	eCordum™ Cardiac Monitor
Regulation Name	Telephone electrocardiograph transmitter and receiver
Regulation Number	21 CFR870.2920
Product Code	DXH
510(k) review	Cardiovascular
Regulatory Class	Class II
510(k) number	K193296

4. Device Description



ECG recorder host | Bluetooth | iOS APP VSHealth

Figure-1 Illustration of VitalSigns 1-Lead Holter

VitalSigns 1-Lead Holter is an ambulatory and Bluetooth-based wireless communication ECG measurement solution designed to allow users to record, store, transmit, and display single-channel ECG data.

VitalSigns 1-Lead Holter consists of the following three components:

(1) VS Electrode Patch “VSP101”

(2) ECG Recorder Host “VSH101”

(3) iOS APP “VSHealth”

When the ECG Recorder Host "VSH101" is fully charged and connected wirelessly via Bluetooth to the iOS app "VSHealth", it can instantly obtain the user's ECG data. VSHealth assists in transmitting, displaying, recording, and storing ECG data.

After the "VSH101" is fully charged, the device, through the VSHealth app, allows users to continuously use and record ECG data for 24 hours in their daily routines, whether at home or in a work environment.

5. Intended Use/ Indication for Use

The VSH101 is designed to record, transmit, and store single channel electrocardiogram (ECG) data via Bluetooth communication to compatible Bluetooth enabled devices. The device is intended for use by healthcare professionals, individuals with known or suspected cardiac conditions, and health-conscious users. The ECG data serves as a supplementary source of patient information and is not intended for automated analysis.

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6. Contraindications

VSH101 is contraindicated for those patients with the following conditions:

- Chronic Disease patients
- Allergic to polyester patient
- Pregnant women, breastfeeding women, infants or children
- Patients with implanted pacemakers or implantable cardioverter defibrillators (ICDs). The device should not be used in the presence of these implants.
- Patients during defibrillation or AED rescue. The device must be removed prior to such procedures.

Caution: The ECG data acquired by the subject device is a non-traditional lead intended only for manual interpretation.

7. Target Population

This product is intended for use in patients 21 years of age or older.

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8. Safety and Effectiveness Substantial Equivalence Comparison

Device Name	VitalSigns 1-Lead Holter	eCordum™ Cardiac Monitor	Substantial equivalence of difference determination
Applicant	VitalSigns Technology Co., Ltd	eCordum, Inc.	--
510(k) Number	K243003	K193296	--
Regulation Number	21 CFR 870.2920	21 CFR 870.2920	***SE***
Product Code	DXH	DXH	***SE***
Classification	Class II	Class II	***SE***
Indication for use	The VSH101 is designed to record, transmit, and store single- channel electrocardiogram (ECG) data via Bluetooth communication to compatible Bluetooth enabled devices. The device is intended for use by healthcare professionals, individuals with known or suspected cardiac conditions, and health-conscious users. The ECG data serves as a supplementary source of patient information and is not intended for automated analysis.	The eCordum™ Cardiac Monitor is intended to record, transfer and store single- channel electrocardiogram (ECG) data via Bluetooth transmission to Bluetooth enabled devices. The monitor is intended for use by healthcare professionals, patients with known or suspected heart conditions and health-conscious individuals. The ECG data is intended to supplement other patient data and is not intended for automated analysis. The device has not been tested and it is not intended for pediatric use.	***SE***
Number of ECG	1 channel	1 channel	***SE***
Power source	Rechargeable Lithium battery pack 3.7V/ 160mAh/ 0.59Wh	Replaceable Coin Battery (CR2032)	Different The battery has been tested and met its pre- defined criteria, and it does not raise new issues of safety and effectiveness.

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Intended use environment	Healthcare and home environments	Healthcare	***Similar*** Predicate device allows ambulatory use and by healthcare professionals. Although home use is not explicitly stated, the functional environment overlap supports similar use conditions
Communication Protocol	Bluetooth Low Energy (2402 – 2480 MHz)	Class II Bluetooth	***Similar*** transmission type
Data storage	24 hours	Not provided	Different There is no change in the safety and effectiveness of the device. Performance is equivalent to IEC 60601-2-47 for all devices.
Viewing software platform	Mobile app	Mobile app	***SE***
Application/ wear	Chest-based, single channel	Chest for ambulatory OTS electrodes	***Similar*** region
Electrodes	The VS Electrode Patch is composed of 3M™ Single-Coated Medical Tan Elastic Nonwoven Tape on Line and AmGel AG600 Series Sensing Hydrogels. Both materials are widely utilized in electrode applications.	Attachable standard ambulatory OTS electrodes with conductive gel.	Different The VS Electrode Patch has been tested in accordance with ANSI/AAMI EC12, confirming compliance with established safety and performance standards. The patch provides stable conductivity, low impedance, and biocompatibility.

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Compliance standard	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-47 IEC 60601-1-11 IEC 10993-1 ANSI/AAMI EC12 FCC testing per part 15	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-47 IEC 10993-1 FCC testing per part 15	***Similar*** The predicate device does not reference ANSI/AAMI EC12 and IEC 60601-1-11. To address the required signal quality, evidence will be generated through the proposed performance verification protocol in this submission.

The VitalSigns 1-Lead Holter has been compared with a predicate device. The subject device has the same indications for use, similar technology/mechanism of action, and similar safety and performance as the predicate device.

Although there are some different specifications between two devices, the software validation, performance test and usability test have been completed to demonstrate that the differences between these parameters would not impact the safety and effectiveness of the subject device. The subject device has also undergone all safety and performance tests, and the results complied with the test requirements.

Therefore, the difference between the subject device and the predicate device did not raise any problem of substantial equivalence. The subject device is substantially equivalent to the predicate device in intended use, safety and performance claims.

Continued on the next page

9. Summary of Non-Clinical Testing

The VitalSigns 1-Lead Holter meet all requirements for all design, biocompatibility, electrical, EMC safety and cybersecurity protection. The VitalSigns 1-Lead Holter pass all testing and supports the claims of substantial equivalence and safe operation.
The VitalSigns 1-Lead Holter was designed and tested for compliance with the applicable clauses of the following standards and USFDA guidance:

- ISO 10993-1
- IEC 60601-1

  Note: VSH101 has been tested and complies with the requirements of Clause 8.5.5.2 – Energy reduction test.

- IEC 60601-1-2
- IEC 60601-2-47
- IEC 60601-1-11
- IEC 62304
- ISO 14971
- IEC 62366-1
- ANSI/AAMI EC 12
- IEEE/ANSI C63.27
- USFDA Guidance, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"
- USFDA Guidance, Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions.
- USFDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Device.

Biocompatibility test

- Biological evaluation of medical device
- *In vitro* cytotoxicity
- Skin irritation
- Skin sensitization were conducted.

Electromagnetic compatibility and electrical safety test

- IEC 60601-1 test
- IEC 60601-1-11 test
- Lithium battery safety test
- IEC 60601-1-2 test

Performance testing

- IEC 60601-2-47 test
- Disposable ECG electrode test

Software

- Recorder-VSH101 validation
- APP-VSHealth validation
- Cybersecurity-Cybersecurity management

HFE/UE

RF Wireless test

10. Conclusion

The VitalSigns 1-Lead Holter is substantially equivalent with respect to safety and effectiveness to the legally marketed predicate device for its intended use. Minor differences between the VitalSigns 1-Lead Holter and the predicate device have no effect on safety or effectiveness, as established through various performance tests.