November 14, 2024

Hinlab SAS
Denys-Michel De Larouzière
President
11 rue Alfred de Musset
Neuilly sur Seine, 92200
France

Re: K241397
Trade/Device Name: Hinscope
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac monitor (including cardiotachometer and rate alarm).
Regulatory Class: Class II
Product Code: MSX, DXN, DQA
Dated: May 17, 2024
Received: October 15, 2024

Dear Denys-Michel De Larouzière:

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,

Stephen C. Browning -S

LCDR Stephen Browning
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)*
K241397

Device Name

Hinscope

Indications for Use *(Describe)*

Hinscope is intended for spot-check vital signs measurement of adult patients in professional healthcare facilities, such as hospitals or skilled nursing facilities. It is intended to be used by trained healthcare professionals.

Hinscope is intended for spot-check measurements, in adults, of:
- Non-Invasive Blood Pressure (NIBP)
- Pulse rate (PR)
- Oxygen saturation (SpO2)

Hinscope is not intended for use in high-acuity environments, such as intensive care units (ICU) or operating rooms.

Hinscope is not intended for use on acutely ill cardiac patients with the potential to develop life-threatening arrhythmias e.g. very fast atrial fibrillation. These patients should be monitored using a device with continuous electrocardiogram (ECG). Hinscope is not a substitute for an ECG monitor.

Hinscope is not intended for SpO2 and PR measurements in conditions of high motion or low perfusion.

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.

hinlab SAS
Traditional 510(k)
For hinscope

510(k) Summary

This 510(k) Summary is submitted in accordance with 21 CFR Part 807, Section 807.92

Submitter's Name: hinlab SAS

Submitter's Address:
11 rue Alfred de Musset
92200 Neuilly sur Seine France
Telephone: +33 (0) 7 69 66 11 68

Contact Person:
Denys-Michel de Larouzière
Chief Executive Officer
Telephone: +33 (0) 7 69 66 11 68

Date Prepared: May 10, 2024

hinlab SAS
Traditional 510(k)
For hinscope

Device Classification Information Regarding hinscope

Primary Product Code:

Regulation Number	Device	Medical Specialty	Product Code	Device Class	Classification Panel
870.2300	System, Network and Communication, Physiological Monitors	Cardiovascular	MSX	Class 2	Cardiovascular

Secondary Product Codes:

Regulation Number	Device	Medical Specialty	Product Code	Device Class	Classification Panel
870.2700	Oximeter	Cardiovascular	DQA	Class 2	Cardiovascular
870.1130	System, Measurement, Blood-Pressure, Non-Invasive	Cardiovascular	DXN	Class 2	Cardiovascular

Device Trade Name: hinscope

Device Common Name: hinscope

Indications for Use

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hinscope is intended for spot-check measurements, in adults, of:
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hinscope is not intended for SpO2 and PR measurements in conditions of high motion or low perfusion.

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Traditional 510(k)
For hinscope

Summary and comparison of technological characteristics

Summary of Substantial Equivalence
The following predicate device has been chosen that hinscope can claim equivalence with and these are detailed below.

General Comparison

Property	Proposed Device hinscope	Primary Predicate Current Wearable Health Monitoring System	Comment
Common Name	System, Network and Communication, Physiological Monitors	System, Network and Communication, Physiological Monitors	N/A
Device Manufacturer	hinlab SAS	Current Health Ltd	N/A
Device Classification	II	II	Identical
510(k) Number	K241397	K191272	N/A
Primary Product Code	MSX	MSX	Identical
Secondary Product Code	DQA DXN	FLL DQA BZQ DRG BZG	Equivalent to primary predicate for claimed measurement parameters
Target Population	Adult	Adult	Identical
Environment	Professional healthcare facilities	Professional healthcare facilities & home	Equivalent. The subject device is intended for use in professional healthcare facilities, which is a subpart of the predicate device's environment. There are no safety or effectiveness concerns arising from these differences.

hinlab SAS
Traditional 510(k)
For hinscope

Property	Proposed Device hinscope	Primary Predicate Current Wearable Health Monitoring System	Comment
Intended Use/Indications for Use	hinscope is intended for spot-check vital signs measurement of adult patients in professional healthcare facilities, such as hospitals or skilled nursing facilities. It is intended to be used by trained healthcare professionals. hinscope is intended for spot-check measurements, in adults, of: - Non-Invasive blood pressure (NIBP) - Pulse rate (PR) - Oxygen saturation (SpO2) hinscope is not intended for use in high-acuity environments, such as intensive care units (ICU) or operating rooms. hinscope is not intended for use on acutely ill cardiac patients with the potential to develop life-threatening arrhythmias e.g. very fast atrial fibrillation. These patients should be monitored using a device with continuous electrocardiogram (ECG). hinscope is not a substitute for an ECG monitor. hinscope is not intended for SpO2 and PR measurements in conditions of high motion or low perfusion.	The Current Wearable Health Monitoring System is intended for reusable bedside, mobile and central multi-parameter, physiologic patient monitoring of adult patients in professional healthcare facilities, such as hospitals or skilled nursing facilities, or their own home. It is intended for monitoring of patients by trained healthcare professionals. The Current Wearable Health Monitoring System is intended to provide visual and audible physiologic multi-parameter alarms. The Current Wearable Health Monitoring System is intended for temperature monitoring where temperature at the upper arm is clinically indicated. The Current Wearable Health Monitoring System is intended for continuous monitoring of the following parameters in adults: Pulse rate Oxygen saturation Temperature Movement The Current Wearable Health Monitoring System is intended for intermittent or spot-check monitoring, in adults, of:	Equivalent. The subject device has similar indications as the predicate for non-invasive blood pressure, pulse rate and oxygen saturation.

Property	Proposed Device hinscope	Primary Predicate Current Wearable Health Monitoring System	Comment
		Respiration rate Non-invasive blood pressure Lung function & spirometry Weight The Current Wearable Health Monitoring System is not intended for use on acutely ill cardiac patients with the potential to develop life threatening arrhythmias e.g. very fast atrial fibrillation. For these patients, they should be monitored using a device with continuous ECG. The Current Wearable Health Monitoring System is not a substitute for an ECG Monitor. The Current Wearable Health Monitoring System is not intended for SpO2 monitoring in conditions of high motion or low perfusion.	

Device Description

hinscope consists of the:

- hinscope measurement unit
- hinscope mobile application

hinscope consists of a vital sign measurement unit, that is positioned on the patient's upper arm, and a mobile application with a user interface which allows display of the vital sign data. hinscope is a combination of optical sensors and a sphygmomanometer cuff which provide measurements of the patient's pulse rate (PR) oxygen saturation (SpO2), and non-invasive blood pressure (NIBP).

PR and SpO2 are measured using a photoplethysmography (PPG) optical measurement method. PPG is a noninvasive technology that uses light sources (green, red and infrared) and photodetectors at the surface of skin to

measure the volumetric variations of blood circulation. Blood pressure is measured with the sphygmomanometer using an algorithm in which the cuff is slowly inflated while simultaneously sensing oscillations. Once oscillations are no longer detected, the cuff deflates rapidly, and the signals are processed to determine systolic and diastolic pressures.

The vital sign measurement device communicates with a mobile application via wireless Bluetooth Low Energy (BLE) communication. The hinlab mobile application displays the blood pressure, SpO2 and pulse rate measurements.

Technological Characteristics
A comparative review of hinscope with the predicate device found that the technology, mode of operation, and general principles for treatment with this device were substantially equivalent to the predicate device.

Conclusion from nonclinical and clinical tests

Non-Clinical Tests (Performance/Physical Data)
Verification and validation activities established the safety and performance of the subject device based on the following tests, which were all passed:

Test Name	Test Description	Results
Electrical Safety	hinscope was tested to confirm that it met the applicable standards for electrical safety (IEC 60601-1).	Passed
EMC	hinscope was tested to confirm that it met the applicable standards for electromagnetic compatibility (EMC) (IEC 60601-1-2).	Passed
Pulse Rate Testing	hinscope was tested to confirm the accuracy of pulse rate monitoring of the system in accordance with ISO 80601-2-61 and the FDA Pulse Oximeters - Premarket Notification Submissions: Guidance for Industry and FDA Staff, 2007.	Passed
Usability Testing	hinscope was assessed with regards to usability for compliance with FDA Guidance Applying Human Factors and Usability Engineering to Medical Devices.	Passed
Biocompatibility Testing	Testing and analysis of hinscope has demonstrated compliance to ISO 10993-1, ISO 10993-5, ISO 10993-10 and ISO 10993-23.	Passed
SpO2 Testing	Ensure the accuracy and communication of the SpO2 functions within hinscope per ISO 80601-2-61 and the FDA SpO2 guidance: Pulse Oximeters - Premarket Notification Submissions Guidance for Industry and Food and Drug Staff, March 4, 2013.	Passed
Wireless Radio Communication (Wireless Coexistence)	hinscope was tested in accordance to USEMCSC C63.27-2021 and TIR69:2017/(R2020) to ensure the device can communicate via wireless radio in its intended environment.	Passed

Test Name	Test Description	Results
System Verification and Validation Testing	The system verification and validation testing was performed to verify the software and firmware of hinscope as recommended by FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Functions" (June 2023).	Passed
Risk Management	hinscope was tested and confirmed to meet all the applicable requirements for application of risk management to medical Device per ISO 14971.	Passed
Software Life Cycle	hinscope was tested and confirmed to meet all the applicable requirements for software life cycle per IEC 62304.	Passed
Non-Invasive Blood Pressure (NIBP) Testing	The device was tested according to IEC 80601-2-30: Medical electrical equipment – Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers.	Passed

Software Verification and Validation Testing
Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Functions" (June 2023).

Animal Studies
No animal studies were conducted as part of submission to prove substantial equivalence.

Clinical Performance Testing
The clinical performance study investigated the accuracy of blood oxygen saturation and pulse rate performance in 13 healthy adult subjects with varying BMIs and diverse skin tones. The study was conducted in accordance with ISO 80601-2-61:2017 and Pulse Oximeters – Premarket Notifications Submissions [510(k)s] Guidance for Industry and Food and Drug Administration Staff (issued: March 4, 2013). The results of the study provide supporting evidence that the SpO2 accuracy performance of hinscope passes the ARMS acceptance criteria of <3.5% under steady state and non-motion conditions for the range 70-100%.

The non-invasive blood pressure (NIBP) validation study was conducted in accordance with the universal standard validation protocol (AAMI/ESH/ISO) as outlined in ISO 81060-2:2018 and its amendment, ISO 81060-2:2018/Amd 1:2020. The study included 85 subjects (41 males, 44 females) with an arm circumference of 22–32 cm. Both validation criteria 1 and 2 were satisfied for SBP and DBP, with a mean NIBP difference inferior or equal to 5 mmHg ± 8 mmHg.

Safety and Effectiveness/Conclusion
Based on the information presented in these 510(k) premarket notifications hinscope is considered substantially equivalent. hinscope is as safe and effective as the currently marketed predicate device.

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Traditional 510(k)
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Based on testing and comparison with the predicate device, hinscope indicated no adverse indications or results.