



November 18, 2025

Carre Technologies Inc.
Jean-François Roy
CTO
5800 St. Denis, Suite 601
Montreal, QC H2S 3L5
Canada

Re: K243981

Trade/Device Name: Hexoskin Medical System (7100-00016)
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitter And Receiver
Regulatory Class: Class II
Product Code: DXH, BZQ
Dated: October 17, 2025
Received: October 17, 2025

Dear Jean-François Roy:

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,
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Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K243981

Device Name
Hexoskin Medical System (7100-00016)

Indications for Use (Describe)

The Hexoskin Medical System (HMS) is intended for use at home, or at a healthcare facility, on the order of a licensed medical professional, to record, display and store the following physiological data: a) 3 leads of electrocardiogram; b) heart rate; c) respiratory rate; and d) activity. The device is intended for use when the clinician decides to evaluate the physiologic signals of adult patients as an aid to diagnosis and treatment. The HMS ECG recordings are indicated for the manual assessment of cardiac rhythm disturbances. The device does not produce alarms and is not intended for active patient monitoring (real-time). The device is not intended for use as life supporting equipment on high-risk patients such as critical care patients. The device is not intended for use in the presence of a pacemaker.

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 HEXOSKIN MEDICAL SYSTEM

1 SUBMITTER INFORMATION

Manufacturer Address

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Canada

Contact

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CTO and Co-Founder
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2 DATE OF PREPARATION: NOVEMBER 14, 2025

3 DEVICE TRADE NAME: HEXOSKIN MEDICAL SYSTEM

4 CLASSIFICATION PRODUCT CODE

21 CFR Reference	Product Code	Class	Classification Name
§870.2920	DXH	2	Transmitters and Receivers, Electrocardiograph, Telephone
§868.2375	BZQ	2	Monitor, Breathing Frequency

5 PREDICATE AND REFERENCE DEVICES

Predicate/ Reference	510(k) No.	Product Code	Device Name	Relevance	Indications for Use
Predicate	K201669	DXH	SimpleSENSE	Substantial equivalent	The SimpleSENSE System is intended for use at home, or at a healthcare facility,

					<p>under the direction of a licensed medical professional, to record, display and store the following physiological data: a) 2 leads of Electrocardiogram; b) Respiration rate measured through thoracic impedance; c) Heart Sounds; and d) Activity including posture. The device is intended for use when the clinician decides to evaluate the physiologic signals of adult patients as an aid to diagnosis and treatment. The SimpleSENSE System is intended to be used by patients at rest and not performing any activities or movements. ECG recordings are indicated for the manual assessment of cardiac rhythm disturbances. The device does not produce alarms and is not intended for active patient monitoring (real-time). The device is not intended for use as life supporting equipment on high-risk patients such as critical care patients. The device is not intended for use in the presence of a pacemaker.</p>
Reference	K173248	DXH	CARDIOSKIN	Similar textile-based ECG electrode made of silver yarns	<p>Cardioskin is intended to aid the diagnostic evaluation for cardiac disorders by recording patient's ECG signals allowing to condition and monitor these signals. ECG data is stored, transferred and displayed for a review by a physician. Cardioskin is designed to be used by a patient to transmit multiple-lead ECG signal to enable review at a physician's office, hospital or other remote locations under medical supervision. Cardioskin target population is adults.</p>
Reference	K013905	MNR	MODIFICATION EZ-1 SYSTEM REPIRATORY SENSORS	Same respiratory inductance plethysmography	<p>The Synchrony amplifier is intended for use with Pro-Tech Quantum respiratory effort sensors during sleep disorder studies for the purpose conditioning, balancing, summing</p>

				(RIP) sensor technology	and amplifying the thoracic and abdominal effort signals.
Reference	K202868	DRG	LifeSignals Multi-Parameter Remote Monitoring Platform	Similar range and accuracy for heart rate and breathing rate	The LifeSignals Multi-parameter Remote Monitoring Platform is a wireless remote monitoring system intended for use by healthcare professionals for continuous collection of physiological data at home and in healthcare settings. This shall include Electrocardiography (2-channel ECG), Heart Rate, Respiration Rate, Skin Temperature & Posture. Data is transmitted wirelessly from LifeSignals Biosensor to Remote secure server for display, storage & analysis. The LifeSignals Multi-parameter Remote Monitoring Platform is intended for non-critical, adult population. The LifeSignals Multi-parameter Remote Monitoring Platform can include the ability to notify healthcare professionals when physiological parameters fall outside the set limits and to display multiple patient physiological data for remote monitoring.

6 DEVICE DESCRIPTION

The HMS consists of four main components - three physical components and one software user interface (UI) component.

The physical components are the HMS Recorder, the HMS Shirt, and the Cable. The Recorder is a rechargeable data acquisition module that connects to the Shirt. The Shirt is available in a wide range of configurations, catering to diverse patient body types and builds. The Cable is a USB to micro-USB cable that connects to the Recorder for data transfer and charging. The UI component is a PC-based, stand-alone software that displays the recordings stored on the Recorder.

This device is not an apnea monitor. Users should not rely on its respiration monitoring for detecting cessation of breathing.

The Hexoskin Medical System does not provide any automatic analysis or diagnosis.

7 INDICATIONS FOR USE

The Hexoskin Medical System (HMS) is intended for use at home, or at a healthcare facility, on the order of a licensed medical professional, to record, display and store the following physiological data: a) 3 leads of electrocardiogram; b) heart rate; c) respiratory rate; and d) activity. The device is intended for use when the clinician decides to evaluate the physiologic signals of adult patients as an aid to diagnosis and treatment. The HMS ECG recordings are indicated for the manual assessment of cardiac rhythm disturbances. The device does not produce alarms and is not intended for active patient monitoring (real-time). The device is not intended for use as life supporting equipment on high-risk patients such as critical care patients. The device is not intended for use in the presence of a pacemaker.

8 SUBSTANTIAL EQUIVALENCE COMPARISON

Table 8-1 Comparison between Subject Device and Predicate (K201669)

Comparison	Subject Device Hexoskin Medical System	Predicate (K201669) SimpleSENSE	Similarities/Differences
Manufacturer	Carré Technologies Inc. (dba Hexoskin)	Nanoware Inc.	/
Primary Product Code	DXH	DXH	Same.
Subsequent Product Codes	BZQ	BZQ, DPS, DQD, DSB	Fewer functions than the predicate does not affect the substantial equivalence of the two functions provided by the subject device.
Regulation Classification (Primary)	21 CFR 870.2920 Class II	21 CFR 870.2920 Class II	Same.
Indications for Use	The Hexoskin Medical System (HMS) is intended for use at home, or at a healthcare facility, on the order of a licensed medical professional, to record, display and store the following physiological data: a) 3 leads of Electrocardiogram; b) heart rate;	The SimpleSENSE System is intended for use at home, or at a healthcare facility, under the direction of a licensed medical professional, to record, display and store the following physiological data: a) 2 leads of Electrocardiogram; b)	Similar. Differences in sensor technologies and recorded parameters are assessed in the corresponding comparison category below.

Comparison	Subject Device Hexoskin Medical System	Predicate (K201669) SimpleSENSE	Similarities/Differences
	c) respiratory rate; and d) activity.	Respiration rate measured through thoracic impedance; c) Heart Sounds; and d) Activity including posture.	
	The device is intended for use when the clinician decides to evaluate the physiologic signals of adult patients as an aid to diagnosis and treatment. The HMS ECG recordings are indicated for the manual assessment of cardiac rhythm disturbances.	The device is intended for use when the clinician decides to evaluate the physiologic signals of adult patients as an aid to diagnosis and treatment. The SimpleSENSE System is intended to be used by patients at rest and not performing any activities or movements. ECG recordings are indicated for the manual assessment of cardiac rhythm disturbances.	Similar. Results of testing submitted demonstrate that the subject device can be used when the patients are performing activities and movements (ambulatory).
	The device does not produce alarms and is not intended for active patient monitoring (real-time). The device is not intended for use as life supporting equipment on high-risk patients such as critical care patients. The device is not intended for use in the presence of a pacemaker.	The device does not produce alarms and is not intended for active patient monitoring (real-time). The device is not intended for use as life supporting equipment on high-risk patients such as critical care patients. The device is not intended for use in the presence of a pacemaker.	Similar. Testing demonstrates that the subject device is not adversely affected by the presence of a pacemaker, and it does not detect or record its activity.
Intended Population	Non-critical adult population	Non-critical adult population	Same.
Intended Use Environment	Home or healthcare facility	Home or healthcare facility	Same.
Sensor Technology and Recorded Parameters			
ECG Sensor	Silver-coated nylon	Textile-based nanosensors	Similar.

Comparison	Subject Device Hexoskin Medical System	Predicate (K201669) SimpleSENSE	Similarities/Differences
			<p>Both devices adopt non-standard textile-based sensors.</p> <p>The subject device uses a sensor technology similar to that of reference device K173248 (textile-based ECG electrode made of silver yarns).</p>
ECG Recording	3-lead	2-lead	<p>Similar.</p> <p>The subject device uses an additional lead. The 3-lead ECG recordings acquired by the subject devices were demonstrated to be comparable to a 3-lead Holter monitor.</p>
Heart Rate	Derived from ECG recordings	N/A	Only ECG recordings are used for manual assessment of cardiac rhythm disturbances, this additional parameter (heart rate) does not affect the intended use of the subject device.
Heart Rate Range	30-220 beats per minute (bpm)	N/A	Similar to reference device K202868 (30-250 bpm).
Heart Rate Accuracy	±5 bpm	N/A	Results of clinical testing submitted demonstrate that the claimed heart rate accuracy is accurate.
Respiratory Sensor	Respiratory inductance plethysmography (RIP) sensor	Textile-based nanosensors	Same RIP sensor technology as reference device K013905 (RIP).

Comparison	Subject Device Hexoskin Medical System	Predicate (K201669) SimpleSENSE	Similarities/Differences
			Used to acquire respiratory waveform only, not for reporting 'respiratory effort'.
Respiratory Rate	Derived from waveform measured by RIP sensor	Derived from thoracic impedance measured by textile-based nanosensors	Results of clinical testing submitted demonstrate that the respiratory rate reported by the subject device is comparable to the gold standard (blinded, manually annotated EtCO ₂ waveform acquired by an FDA-cleared capnogram (K063752)).
Respiratory Rate Range	2-60 breaths per minute (BPM)	6-22 breaths per minute (BPM)	Similar. The subject device was tested to be comparable when patients were performing activities (i.e., in a higher respiratory rate range).
Respiratory Rate Accuracy (at rest)	±2 BPM	±2 BPM	Same.
Respiratory Rate Accuracy (under motion conditions (e.g., walking))	±3 BPM	N/A	Results of testing submitted demonstrate that the subject device has an accuracy of ±3 BPM when patients were performing moderate activities (e.g., walking). This accuracy is also the same as reference device K202868 (±3 BPM).
Heart Sound	N/A	MEMS microphone	The subject device does not record heart sound, which is not

Comparison	Subject Device Hexoskin Medical System	Predicate (K201669) SimpleSENSE	Similarities/Differences
			a required parameter for the claimed intended use.
Activity	Accelerometer	Accelerometer Including posture	Similar. The subject device does not record posture, which is not a required parameter for the claimed intended use.
Display Requirement	User provided display hardware for a healthcare professional to view the recorded data. A general-purpose PC/Laptop/Desktop may be used.	User provided display hardware for a healthcare professional to view the recorded data. A general-purpose PC/Laptop/Desktop or mobile device may be used.	Similar. The subject device only provides a PC/Laptop/Desktop-based UI application. This has no impact on the claimed intended use.
Power Source	Internally powered using Li-Ion rechargeable battery.	Internally powered using Li-Ion rechargeable battery.	Same.
Internal Memory/Data	Non-removable MicroSD card	Removable MicroSD card	The usage of non-removable versus removable MicroSD card does not alter the performance or add any risks to the device.
Communication Interface	In the current model, Bluetooth will be used only for software maintenance; data transfer is achieved via USB.	Wireless transceiver using Bluetooth.	The usage of wire versus wireless transceiver does not alter the performance or add any risks to the device.
Access to Recorded Data	Data is transferred to a PC/Laptop/Desktop, which is then viewed by the healthcare professional. For redundancy, encrypted data is also stored in the storage medium.	Data is transferred to the iPhone, which is then shared with the healthcare professional. For redundancy, encrypted data is also stored in the removeable storage medium.	The usage of PC/Laptop/Desktop versus iPhone for data transfer does not alter the performance or add any risks to the device.

9 PERFORMANCE TESTING – BENCH

Performance testing was conducted on Hexoskin Medical System to demonstrate substantial equivalence to the predicate device, including:

- Biocompatibility (3rd-party testing)
 - ISO 10993-1 (FDA Recognition No. 2-258)
 - ISO 10993-5 (FDA Recognition No. 2-245)
 - ISO 10993-10 (FDA Recognition No. 2-174)
 - ISO 10993-18 (FDA Recognition No. 2-276)
- Cybersecurity testing (3rd-party testing)
- Electromagnetic Compatibility (3rd-party testing)
 - IEC 60601-1-2 (FDA Recognition No. 19-36)
 - IEC 60601-4-2 (FDA Recognition No. 19-19)
- Basical Safety and Essential Performance (3rd-party testing, ASCA-accredited testing lab)
 - ANSI AAMI 60601-1 (FDA Recognition No. 19-46)
 - IEC 60601-1-6 (FDA Recognition No. 5-132)
 - ANSI AAMI 60601-1-11 (FDA Recognition No. 19-47)
 - ANSI AAMI IEC 60601-2-47 (FDA Recognition No. 3-155)
- Electromagnetic Compatibility (3rd-party testing)
 - IEC 60601-1-2 (FDA Recognition No. 19-36)
 - IEC TR 60601-4-2 (FDA Recognition No. 19-19)
- Bench Performance (manufacturer testing)
 - Garment quality testing
 - Recorder testing
 - Signal testing
 - Usability testing
- Clinical Performance (manufacturer testing)
 - ECG clinical study
 - Breathing rate clinical study

10 PERFORMANCE TESTING – CLINICAL

Two clinical studies were conducted on the intended patient population to validate the clinical performance of the HMS. Specifically, an ECG clinical study was conducted to compare the ECG recordings acquired by the subject device against signals acquired by a Holter monitor. Additionally, a breathing rate clinical study was performed to assess the breathing rate accuracy against an EtCO₂ device.

10.1 ECG STUDY

The HMS ECG Clinical Validation Study is a single-arm study in which each patient served as their own control, with the Holter monitor as the reference comparator. The study assessed the Hexoskin Medical System (HMS) for its intended use in manual cardiac rhythm assessment using ECG recordings. Fifty-two (52) non-critical adult participants suspected of or diagnosed with arrhythmias simultaneously wore the HMS and a reference Holter monitor for ECG recording during 5-minute and 24-hour sessions. Results demonstrated agreement between HMS and Holter monitor readings for several ECG waveform intervals and heart rate. The study concluded that HMS is accurate, reliable, and safe for its intended use as compared to the predicate.

Basic subject demographics: 52 non-critical adults (mean age 54.7 ± 15.7 years); 29 female (56%) and 23 male (44%); BMI: 29.1 ± 7.7 kg/m². Race: White 32/52 (62%), Asian 13/52 (25%), Black or African American 4/52 (8%), Other/Multiracial 3/52 (6%). Ethnicity: Not Hispanic or Latino 48/52 (92%); Hispanic or Latino 4/52 (8%). Diagnosis status: previously diagnosed with non-critical arrhythmia or heart disease 22/52 (42%); suspected of non-critical arrhythmia but without prior diagnosis 30/52 (58%).

10.2 BREATHING RATE STUDY

The Breathing Rate Study is a single-arm study in which each patient served as their own control, with the capnograph as the reference comparator. The study assessed the accuracy of respiratory rate measurements from the Hexoskin Medical System (HMS) using respiratory inductance plethysmography (RIP) technology, compared to a gold-standard capnograph. Fifty (50) adult participants, including healthy individuals and those with non-critical respiratory conditions, completed tasks ranging from lying down to brisk walking. Results showed the HMS met accuracy requirements, with Root Mean Square Accuracy (Arms) errors within ± 2 bpm for static use and ± 3 bpm under light and moderate motion conditions (i.e., walking at a slow pace and at a brisk pace).

Basic subject demographics: 50 non-critical adults (mean age 49.3 ± 19.0 years); 20 female (40%) and 30 male (60%); BMI 27.5 ± 7.0 kg/m². Reported mild comorbidities: COPD (n=5), asthma (n=6), cardiac condition (n=2).

11 CONCLUSION

The substantial comparison in Section 8 demonstrates direct equivalence between the Indications for Use Statement of the Hexoskin Medical System and the predicate device. Both devices are wearables utilizing a textile-based harness or shirt embedded with sensors to capture, record, and transmit physiological data via an attached hardware recorder module.

Both devices are intended for use in homes or healthcare facilities by non-critical adult populations. They serve as aids to diagnosis and treatment, specifically for the manual assessment of ECG recordings.

The technological characteristics of the Hexoskin Medical System and the predicate/reference devices are identical or largely similar. Testing results indicate that the device's functional performance meets acceptance requirements. Clinical performance testing validates the Hexoskin Medical System's ECG recording performance for its intended use.

In conclusion, Carré Technologies asserts that the Hexoskin Medical System is substantially equivalent to the predicate device.