October 12, 2017

Creavo Medical Technologies, Ltd.
% Sharon Timberlake
Consultant
Halloran Consulting Group, LLC
266 Summer Street
8th Floor
Boston, Massachusetts 02210

Re: K170154
Trade/Device Name: Creavo Vitalscan Magnetocardiograph
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: September 11, 2017
Received: September 12, 2017

Dear Sharon Timberlake:

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 (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. 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.

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 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Nicole G. Ibrahim -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K170154

Device Name

Creavo Vitalscan Magnetocardiograph

Indications for Use *(Describe)*

The Creavo Vitalscan Magnetocardiograph is intended for use as a tool which non-invasively measures and displays the magnetic signals produced by the electric currents in the heart.

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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510(k) Summary

This 510(k) summary is being submitted in accordance with 21 CFR 807.92

1. Submitter's Information

Name: Creavo Medical Technologies Ltd.

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Contact: Sharon Timberlake, MSHS, RAC, CCRA
Halloran Consulting Group, Inc.
Phone: (617) 957-1434
Email: stimberlake@hallorancg.com

Date Prepared: September 11, 2017

2. Device Information

Trade/Propriety Name:	Creavo Vitalscan Magnetocardiograph
Common/Usual Name:	Magnetocardiograph
Classification Name:	Electrocardiograph (21 CFR 870.2340)
Product Code:	DPS

3. Predicate Device

CardioMag Imaging, Inc.
CMI 2409 Magnetocardiograph
510(k) No.: K033488

4. Indications for Use

The Creavo Vitalscan Magnetocardiograph is intended for use as a tool which non-invasively measures and displays the magnetic signals produced by the electric currents in the heart.

5. Device Description

The Creavo Vitalscan Magnetocardiograph is a transportable device, when not in use, which includes a scan head containing multiple sensors, a moveable arm, electronics, software, user touch screen, power supply, and a rechargeable battery. The wheeled chassis and handles allow the device to be transportable between patient beds. During use, the device is placed adjacent to the patient bed.

The color touch screen allows the user to enter patient information (e.g., patient name and scan information) and serves as the visual display unit of the numerical and graphical results during testing. The device also incorporates the use of single use standard ECG electrodes and reusable AHA patient lead wires. The ECG electrodes, are used for gating of the magnetocardiograph signal with the patient's cardiac electrical signal and are used to assist triggering the device electronics and software.

6. Performance Data Summary

Creavo Vitalscan Magnetocardiograph has successfully undergone and passed the following standards testing for the device:

- IEC 60601-1-2:2007: Medical electrical equipment-- Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility - Requirements and tests

- IEC 60601-1:2005+A1:2012: Medical electrical equipment-- Part 1: General requirements for basic safety and essential performance.

- IEC 60601-1-6:2010 + A1:2013: Medical electrical equipment Part 1-6 General requirements for safety - Collateral Standard: Usability

- IEC 62366: 2007+A1: 2014 Medical devices – Application of usability engineering to medical devices.

The overall final testing on the subject device which included electromagnetic compatibility and electrical safety tests, performance tests, software validation and usability data successfully demonstrated that the design specifications were met and does not raise any new concerns that would adversely affect the safety and effectiveness with respect to the predicate device, thus supporting substantial equivalence. The data generated from this testing demonstrates that the Creavo Vitalscan performed as intended and can successfully record a magnetocardiogram in an unshielded hospital environment.

7. Technological Characteristics Comparison

Table 1 compares the similarities and differences between the Creavo Vitalscan Magnetocardiograph and its predicate device. The Creavo Vitalscan Magnetocardiograph is substantially equivalent to its predicate device based on the indications for use, specifications, and function between the devices.

Table 1: Comparison of Characteristics of Subject Device with Predicate Device

Specification	Creavo Vitalscan Magnetocardiograph (subject device)	CMI 2409 Magnetocardiograph (predicate device)	Similar	Different
Intended Use	The Creavo Vitalscan Magnetocardiograph is intended for use as a tool which non-invasively measures and displays the magnetic signals produced by the electric currents in the heart.	The CMI Magnetocardiograph is intended for use as tool which non-invasively measures and displays the magnetic signals produced by the electric currents in the heart.	X	
Transportable Device	Yes	No		X
Shielded Room	Not required	Not Required	X	
Environmental Exclusion Criteria	No Exclusion (Vitalscan is tolerant to ferrous material and electromagnetic interference)	Minimum distances specified to ferrous material (e.g. beds chairs) and sources of interference (e.g. fluorescent light monitors)		X
Patient Bed as Part of Device	No	Yes Magnetically inert bed required		X
Electrical Requirements	115/230 VAC; 3.0A/6.0A; 50/60Hz	100/120/230/240 VAC; 2A/1.5A/1.5A/1.0A; 50/60 Hz	X	
# of ECG lead(s)	3	3	X	
Type of Signal	Magnetic	Magnetic	X	
Magnetic Field Localization	Yes	Yes	X	
Magnetic Detector/Sensor Type	Yes	Yes	X	
# of Magnetic Detectors/ Sensors	37 sensor/channel device with induction coil sensors	9 sensors that require four different 90 second scans (effectively 36 with re-positioning)		X
Sensor Environment	Induction coil device: Functions at room temperature. 10-34 ℃	SQUID device: Functions in liquid helium cryogenic system. -269 ℃		X
Cryogen Used	None	Liquid Helium		X

8. Statement of Substantial Equivalence

The Creavo Vitalscan Magnetocardiograph described in this submission is substantially equivalent to the predicate device CMI 2409 Magnetocardiograph (K033488) manufactured by CardioMag Imaging, Inc. and does not raise new questions in regards to safety or effectiveness with respect to the design, device characteristics, performance testing and intended use.

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