AMCG Co., Ltd.
Soyeon Kim
Senior Regulatory Affairs
F8, 156, Seochojungang-ro, Seocho-gu
Seoul, 06605
Korea, South

Re: K232823
Trade/Device Name: Mcg-s (am1000)
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: February 26, 2024
Received: February 26, 2024

Dear Soyeon Kim:

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.

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,

Kimberly Crowley

For: 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)*

K232823

Device Name

MCG-S (AM1000)

Indications for Use *(Describe)*

AM1000 is intended for use as a tool which non-invasively measures and displays the magnetic signals produced by the electric currents of 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.

510(k) Summary

This 510(k) Summary is being submitted in according with requirement of 21 CFR Part 807.92.

Submitter's Name	AMCG Co., Ltd.
Submitter's Address	F8, 156, Seochojungang-ro, Seocho-gu, Seoul, Republic of Korea
Submitter's Telephone number	+82-2-598-8001
Contact Person	Soyeon Kim AMCG Co., Ltd. +82-2-598-8001
Date Summary was Prepared	September 08, 2023
Trade or Proprietary Name	MCG-S (AM-1000)
Common or Usual Name	Magnetocardiograph
Classification	Class II per 21 CFR §870.2340
Product Code	DPS
Classification Panel	Cardiovascular

1. Device Description

AMCG′s MCG-S will be used for purpose of measurement and analysis in adult cardiology.

Magnetocardiography (MCG) is a non-invasive, non-contact, radiation-free, multichannel body surface mapping technique to record biomagnetic signals of X- and Y-components from the heart generated by the same ionic currents underling the electrocardiogram.

This system consists of Dewar with 96-channel SQUIDs, gantry, electronics, power supply device, and software. 48 of these SQUID sensors are used for detecting the X-components, and the remaining 48 sensors are for the Y-components of the magnetic field. The device does not measure and/or display the magnetic field in the Z-component.

The system increases the output signal of the SQUID by applying the DROS (Double Relaxation Oscillation SQUID) method to increase the measurement sensitivity of the cardiac magnetic field signal, and a wide range of channel area is applied to measure the magnetic field area throughout the heart within a short time. In addition, in order to minimize the mechanical vibration of the sensor, the sensor is installed in a vacuum area, and Dewar, which has excellent noise shielding and insulation performance, is applied.

The system is controlled through noise-free optical fiber signals and can control, measure, process and analyze signals through software.

2. Indications for Use

AM1000 is intended for use as a tool which non-invasively measures and displays the magnetic signals produced by the electric currents of the heart.

3. Technological Characteristics

MCG-S(AM1000) is substantially equivalent in terms of indications for use, technical characteristics, and performance to predicate device (K121825) .

Table 1. Predicate Device

K number	Proprietary Name	Manufacturer	Predicate Type
K121825	CS-MAGII	BIOMAGNETIK-PARK GMBH	Predicate device

Similar or different technical characteristics exist to MCG-S (AM1000), a predicate device.

The following technological differences exist between the subject and predicate device:

Table 2. Comparison Table to Predicate Device

Elements of Comparison	MCG-S (AM1000) (Subject Device)	CS-MAGII (K121825)	Same	Similar
Regulation Number No.	21CFR 870.2340	21CFR 870.2340	X	
Product Code	DPS	DPS	X	
Indications for use	AM1000 is intended for use as a tool which non-invasively measures and displays the magnetic signals produced by the electric currents of the heart.	The BMP MCG CS-MAGII 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	
Type of use	Prescription Use only	Prescription Use only	X	
Description	AMCG's MCG-S will be used for purpose of measurement and analysis in adult cardiology. Magnetocardiography (MCG) is a non-invasive, non-contact, radiation-free,	The BMP MCG CS-MAGII system will be used for diagnostic purposes in adult cardiology. Magnetocardiography (MCG) is a non-invasive, non-contact, radiation-free,		X

Elements of Comparison	MCG-S (AM1000) (Subject Device)	CS-MAGII (K121825)	Same	Similar
	multichannel body surface mapping technique to record biomagnetic signals of X- and Y-components from the heart generated by the same ionic currents underling the electrocardiogram. This system consists of Dewar with 96-channel SQUIDs, gantry, electronics, power supply device, and software. 48 of these SQUID sensors are used for detecting the X-components, and the remaining 48 sensors are for the Y-components of the magnetic field. The device does not measure and/or display the magnetic field in the Z-component. The system increases the output signal of the SQUID by applying the DROS (Double Relaxation Oscillation SQUID) method to increase the measurement sensitivity of the cardiac magnetic field signal, and a wide range of channel area is applied to measure the magnetic field area throughout the heart	multichannel body surface mapping technique to record biomagnetic signals from the heart generated by the same ionic currents underling the electrocardiogram. Compared to electrocardiography (ECG), MCG has similar morphological features such as T-, P-, and Q-waves, and the QRS complex. The advantages of MCGs over traditional EGGs are increased sensitivity to weak signals, lack of distortion from conductivity in body tissues, and presentation of direct current (DC) component signals and primary currents.		

Elements of Comparison	MCG-S (AM1000) (Subject Device)	CS-MAGII (K121825)	Same	Similar
	within a short time. In addition, in order to minimize the mechanical vibration of the sensor, the sensor is installed in a vacuum area, and Dewar, which has excellent noise shielding and insulation performance, is applied. The system is controlled through noise-free optical fiber signals and can control, measure, process and analyze signals through software.			
Target population	Adult	Adult	X	
Configurations	Dewar, Gantry, Electronics(Electric module, DC Power filter module, Power supply device), Software	SQUID gradiometer, Insert, Dewar, Electronics, Software, Gantry and Bed		X
Sensor Type	SQUID(DROS)	SQUID(DROS)	X	
Shielded Room	Required	Required	X	
Cryogen Used	Liquid Helium	Liquid Helium	X	
Helium reliquefied system	Not applicable	Not applicable	X	
Operating System	Windows 10	Windows	X	
Number of SQUID channels	96 channels	64 channels		X
SQUID gradiometer sensitivity	less than 10 fTrms/√Hz (at 100 Hz)	3.5 fTrms/√Hz (at 100 Hz)		X
Sampling rate	1-10 kHz	1 kHz		X

Elements of Comparison	MCG-S (AM1000) (Subject Device)	CS-MAGII (K121825)	Same	Similar
Liquid He volume	13 L	40 L		X
Liquid He Boil-off and refill interval	about 4 days	7 days		X
Liquid He Boil-off Rate	less than 3.5 L/day	Average 4.41 L/day		X
Baseline	50 mm	70 mm		X
Sensing Coil (Detecting Coil)	1st planar gradiometer (X- and Y-component)	1st axial gradiometer (Z-component)		X

Therefore, the differences between the subject device MCG-S(AM1000) and the predicate device do not raise new questions of the safety and effectiveness.

4. Performance Data

MCG-S(AM1000) has been extensively tested in Electromagnetic Compatibility and Electrical Safety, and bench testing.

1) Electromagnetic Compatibility and Electrical Safety

The electromagnetic and electrical safety of MCG-S(AM1000) was tested according to IEC 60601-1 and IEC 60601-1-2 to guarantee that the device meets electromagnetic compatibility and electrical safety requirements.

2) Software

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

3) Performance

Performance tests were conducted to evaluate the basic performance. Following tests were performed and met the internal criteria.

- Sensitivity Test
- L-He Boil-off Rate Test
- Dimensional Test
- Sensor Operation Test
- Accuracy Test
- Heart Positioning Test
- Heart Rate Measurement Test
- Sensor Calibration Test

5. Summary of Substantial Equivalence

Based on the comparison, we have demonstrated that MCG-S (AM1000) has been shown to be as safe and effective for the proposed Indications for Use as the legally marketed predicate device. Therefore, we conclude that the proposed MCG-S (AM1000) is substantially equivalent to those predicate device.

6. Conclusion

The results of safety and performance tests demonstrate the substantial equivalence of MCG-S (AM1000). There are some differences with the predicate device, however, the differences between the subject device MCG-S (AM1000) and the predicate device do not raise new questions of the safety and effectiveness. Therefore, MCG-S (AM1000) is substantially equivalent to the predicate device and does not raise any new issues regarding safety or efficacy when compared to its predicate device.