DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 18, 2016

MedFact Engineering GmbH
% Melissa Walker
President & Cto
Graematter, Inc
1324 Clarkson Clayton Ctr, #332
Ballwin, Missouri 63011

Re: K151139
Trade/Device Name: EasyMap MAP Catheter
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter or Electrode Recording Probe
Regulatory Class: Class II
Product Code: DRF
Dated: September 11, 2016
Received: September 13, 2016

Dear Melissa Walker:

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.

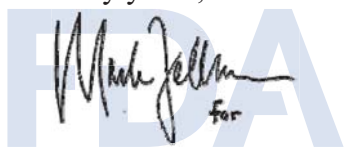
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 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 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 yours,



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)* K151139

Device Name
EasyMap MAP Catheter

Indications for Use *(Describe)*
EasyMap MAP catheters are indicated for simultaneously pacing and recording Monophasic Action Potentials (MAPs) from the endocardial surface of the human 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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Appendix 1: 510(k) Summary per 21CFR §807.92

Submitter's information

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Contact: Melissa Walker
Graematter, Inc.
1324 Clarkson Clayton Ctr #332
Ballwin, MO 63011
Phone: 636-405-7498
Date: 04/20/2015

Device/ classification name

Classification information for the EasyMap MAP Catheter follows:

- 21 CFR 870.1220
- Product Code DRF
- Classification/Common name: Electrode recording catheter or electrode recording probe

The marketed device(s) to which substantial equivalence is claimed:

- Franz Steerable Combination Catheter 510(k)
- K903880 cleared October 12, 1990.

Device description

EasyMap MAP is a single-use disposable quadropolar catheter for recording monophasic action potentials and for intracardial pacing. Integrated in the catheter tip are a Silver-Chloride Electrode (AgCI), a Silver Electrode (Ag) and two orthogonally placed Silver Electrodes (Ag). These electrodes enable mapping of cardiac electrochemical potentials.

The catheter tip can be deflected in a single direction up to 270 degrees.

Indications for use

EasyMap MAP catheters are indicated for simultaneously pacing and recording monophasic Action-Potentials (MAPs) from the endocardial surface of the human heart.

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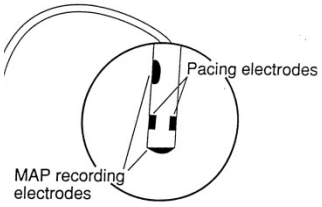
Appendix 1: 510(k) Summary per 21CFR §807.92, Continued

Comparison matrix of basic key characteristics

The table below lists the main characteristics of the proposed EasyMap MAP Catheter compared to the Predicate Franz MAP Catheter. The Franz MAP Catheter was chosen as the predicate device because the intended use is identical to the EasyMap MAP Catheter in that both are designed to detect and record electrical potentials from the endocardial surfaces of the heart and to deliver externally generated pacing stimuli.

Device Characteristic	Franz Steerable Combination Catheter Predicate Device K903880	Proposed New Device: EasyMap MAP Catheter
Physiologic purpose	Aid physician in management of arrhythmias	same
Intended for use by	Cardiac EP or cardiovascular surgeons	same
Primary function	MAP recording and temporary cardiac pacing	same
Insertion method	Percutaneous through a large vein by Seldinger technique	same
Electrode material	MAP: AG/AgCl Pacing: Platinum	same
No. of electrodes	4-8 electrodes 2 MAP 2-6 Pacing	4 electrodes 2 MAP 2 Pacing
Electrode spacing - 	MAP electrodes 4.5 mm edge to edge	MAP electrodes 4.5 mm edge to edge
	Pacing electrodes 3.6 mm (center to center), 1.6 mm (edge to edge)	Pacing electrodes 3.6 mm (center to center) 1.6 mm (edge to edge)
Sterile	Yes	same
Method of sterilization	EO gas	same
Single use	Yes	same
Catheter body material	Pebax	Pebax
Catheter diameter	5, 6, 7 F	7F
catheter length	80-150 cm	110 cm
Tip deflection angle/ range	270º in two directions	Unidirectional up to 270º

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Appendix 1: 510(k) Summary per 21CFR §807.92, Continued

Test summary

The table below lists the applied standards and test results for the EasyMap MAP Catheter.

Test	Applied Standard	Result
Corrosion Test	ISO 10555	Passed Test
Dimension Tests	Internal Test Method	Passed Test
Electrical Tests - Continuity - Short Circuit - Isolation/Leakage Test - High Voltage Test (1 kV)	EN 60601	Passed Test
Mechanical Test - Mechanical Strength after moisture storage - Steerability - Fixation Push / Pull Control	 ISO 10555 Internal Test Method Internal Test Method	Passed Test
Compatibility with existing products - Bending - Dimensions	Internal Test Method	Passed Test
Biocompatibility	ISO 10993	Passed Test
Shelf Life Test	Internal Test Method	Passed Test
Packaging Validation	ISO 11607-1	Passed Test
Sterilization Validation	EN 550; ISO11135	Passed Test
X-Ray Test / Visibility	Internal Test Method	Passed Test

Note: Tests are to be performed on sterilized products after storage and moisture (0.9% NaCl water bath 37 °C, 24 h) Thermal Shock Test and bending performance test.

Performance data

Based upon the documentation presented in this 510(k) it has been demonstrated that the EasyMap MAP Catheter is safe and effective for its intended use.