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

September 9, 2014

Topera, Inc.
% Dennis Pozzo
Senior Regulatory Affairs Master Specialist
3668 S. Geyer Road, Suite 365
St. Louis, Missouri 63127

Re: K142182
Trade/Device Name: FIRMap Mapping Adapter Connector (MAC)
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter Or Electrode Recording Probe
Regulatory Class: Class II
Product Code: MTD
Dated: August 8, 2014
Received: August 11, 2014

Dear Dennis Pozzo,

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.

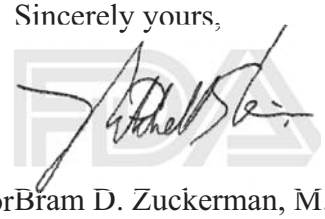
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Appendix 2: Indications for Use Statement

The following page contains FDA Form 3881 regarding the Indications for Use for the FIRMap™ MAC.

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)*
K142182

Device Name

FIRMap Mapping Adapter Connector (MAC)

Indications for Use *(Describe)*

The Topera FIRMap™ Mapping Adapter Connector (MAC) is indicated for use with Topera's FIRMap™ Catheters in cardiac electrophysiology procedures. Refer to the individual Instructions for Use of the associated FIRMap Catheter. It is important to carefully review the specific indications included with the associated catheters prior to use.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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

Submitter's information

Topera, Inc.
3668 S. Geyer Rd, Ste 365
St. Louis, MO 63127
Contact: Dennis Pozzo
Phone: 314-300-6580

Device/ classification name

- Device Name: FIRMap™ Mapping Adapter Cable (MAC)
- Classification/Common name: Catheter, Intracardiac, High Density Array
- The marketed device(s) to which substantial equivalence is claimed: FIRMap Catheter 510(k) – K130827, cleared 10/31/2013

Device description

The FIRMap™ MAC is a re-usable, non-sterile, non-patient contact device that is intended to be used in conjunction with the FIRMap™ catheter. The MAC acts as an interface between the catheter and electrophysiology recording system by connecting the extension cable to the EP system fan out cable.

Indications for use

The Topera FIRMap™ MAC is indicated for use with Topera's FIRMap™ Catheters in cardiac electrophysiology procedures. Refer to the individual Instructions for Use of the associated FIRMap Catheter. It is important to carefully review the specific indications included with the associated catheters prior to use.

Comparison of key characteristics

The FIRMap™ MAC and FIRMap™ Catheter Cables have numerous similarities, both in their intended use and mode of operation.

- Both are re-usable connectors.
- Both are intended to act as an interface between the catheter and electrophysiology recording system.
- Both assemblies deliver electrical signals from the heart to an external diagnostic system.
- Both assemblies are capable of delivering externally generated pacing stimuli.

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

Performance data

The MAC has undergone the following battery of tests:

- Electromagnetic Compatibility
- Continuity and Hi Pot
- Mate De-Mate Cycle
- Mate De-Mate Force

Based upon the test data, it has been demonstrated that the MAC is safe and effective for its intended use.