February 25, 2019

AtriCure, Inc.
Melissa Smallwood
Regulatory Affairs Specialist
7555 Innovation Way
Mason, Ohio 45040

Re: K190151
Trade/Device Name: COBRA Fusion Ablation System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: OCL
Dated: January 28, 2019
Received: January 30, 2019

Dear Melissa Smallwood:

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. 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 located 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.

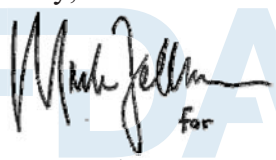
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,



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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190151

Device Name
COBRA Fusion® ablation system

Indications for Use *(Describe)*

The COBRA Fusion® ablation system is intended to ablate cardiac tissue during cardiac surgery using radiofrequency (RF) energy when connected directly to the Electrosurgical unit (ESU).

The COBRA Fusion Pacing/Recording Adapter Cable may be used for temporary cardiac pacing, sensing, recording, and stimulation during the evaluation of cardiac arrhythmias during surgery when connected to a temporary external cardiac pacemaker or recording device.

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.

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

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"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."

510(k) Summary

I. Applicant Information

Manufacturer: AtriCure®, Inc.
7555 Innovation Way
Mason, Ohio 45040
P: 513-644-4736
F: 513-895-9013

Contact Person: Melissa Smallwood
Regulatory Affairs Specialist

Date Prepared: 01/28/2018

II. Device Information

Proprietary Name: COBRA Fusion® ablation system

Common Name: Cardiac Ablation System

Classification: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II; per 21 CFR 878.4400
Product Code: OCL
Classification Panel:

Predicate Device: COBRA Fusion ablation system
(K113475, March 20, 2012)

III. Device Description

The COBRA Fusion ablation system consists of a single use, sterile, ablation probe with integrated suction to engage the tissue during the ablation procedures; single use, sterile, magnetic retriever system to facilitate introduction and advancement of the probe, a temporary external pacing cable and an electrosurgical unit with accessories.

This CBE Special 510(k) contains labeling modifications that do not change the intended use, or the Indications for Use of the device as previously cleared. There are no changes to the labels affixed to the device or the packaging.

IV. Intended Use/ Indications for Use

The COBRA Fusion® ablation system is intended to ablate cardiac tissue during cardiac surgery using radiofrequency (RF) energy when connected directly to the Electrosurgical unit (ESU).

The COBRA Fusion Pacing/Recording Adapter Cable may be used for temporary cardiac pacing, sensing, recording, and stimulation during the evaluation of cardiac arrhythmias during surgery when connected to a temporary external cardiac pacemaker or recording device.

V. Comparison of Technological Characteristics

- The devices have the same intended use, and indications for use;
- The fundamental scientific technology and operating principles remain the same;
- The device has the same design and configuration;
- There is no change to device materials or biocompatibility;
- No changes were made to the packaging and sterilization;
- No changes were made to performance specifications; and
- Verification and validation testing remain applicable to the device.

Modifications included in the COBRA Fusion ablation system Special 510(k) were added for clarification to the existing device instructions for use regarding anticoagulation; the Indications for Use and Intended Use remain the same as previously cleared per K113475.

VI. Performance Data

Appropriate testing has been performed to ensure that device meets its product specifications. Mechanical and reliability testing for the device remain applicable as there are no changes to the device specifications. There are no changes to the patient contact materials so biocompatibility testing as previously established remains applicable. Packaging, sterilization, pyrogen and transit testing performed remain representative of the device in packaged form. There are no changes to the ESU and prior validation and electrical testing remain valid.

Non-clinical Bench Testing previously conducted per K113475 remains applicable as follows:

- Reliability Testing
- Transit
- Shelf-life
- Packaging
- Sterilization
- Mechanical testing
- Biocompatibility
- Electrical Testing (ESU)

VII. Conclusions

The modified COBRA Fusion ablation system is substantially equivalent to the current legally marketed COBRA Fusion ablation system cleared per K113475.
