DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 18, 2016

AtriCure, Inc.
Mr. Jonathan McElwee
Senior Regulatory Specialist
6217 Centre Park Drive
West Chester, Ohio 45069

Re: K160454
Trade/Device Name: AtriClip LAA Exclusion System with Preloaded Gillinov-Cosgrove Clip
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable Clip
Regulatory Class: Class II
Product Code: FZP
Dated: February 17, 2016
Received: February 18, 2016

Dear Mr. McElwee:

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

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)*
K160454

Device Name
AtriClip® LAA Exclusion System with Gillinov-Cosgrove® Clip

Indications for Use *(Describe)*
The AtriClip® LAA Exclusion System is indicated for the occlusion of the heart's left atrial appendage, under direct visualization, in conjunction with other open cardiac surgical procedures.

Direct visualization, in this context, requires that the surgeon is able to see the heart directly, without assistance from a camera, endoscope, etc., or any other viewing technology. This includes procedures performed by sternotomy (full or partial) as well as thoracotomy (single or multiple).

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.

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510(k) Summary

I. Submitter

Manufacturer: AtriCure, Inc.
6217 Centre Park Drive
West Chester, OH 45069
P: 513-755-4100
F: 513-755-4108

Contact Person: Jonathan McElwee
Senior Regulatory Affairs Specialist

Alternate Contact: Jim Taufen
Sr. Manager of Regulatory Affairs

Date Prepared: 2/17/2016

II. Device

Name of Device: AtriClip® LAA Exclusion System with preloaded Gillinov-Cosgrove® Clip (PRO2)

Common Name: Implantable Clip and Clip Applier

Classification Name: Implantable Clip and Clip Applier (21 CFR 878.4300)

Regulatory Class: Class II

Product Code: FZP

III. Predicate Device

The device proposed for modification in this submission is the AtriClip LAA Exclusion System cleared via K122276 on August 29, 2012.

The predicate device has not been subject to a design-related recall.

The following reference devices were also used in this submission:

- K093679 AtriClip LAA Exclusion System with Preloaded Gillinov-Cosgrove Clip
- K131107 AtriClip LAA Exclusion System with Preloaded Gillinov-Cosgrove Clip
- K142120 AtriClip LAA Exclusion System with Preloaded Gillinov-Cosgrove Clip
- K150996 AtriClip LAA Exclusion System with Preloaded Gillinov-Cosgrove Clip
- K153500 AtriClip LAA Exclusion System with Preloaded Gillinov-Cosgrove PRO·V Clip

IV. Device Description

The AtriClip PRO2 LAA Exclusion System consists of a single use, sterile, self-closing, implantable Clip preloaded on a Single Use Clip Applier along with a selection guide. When closed, the Clip applies uniform pressure over the length of the Clip to ensure consistent, reproducible, and secure occlusion of the left atrial appendage (LAA). The clip is then deployed and is left as a permanent implant. The Clip is available in the following lengths to accommodate different sizes of LAA: 35 mm, 40 mm, 45 mm, and 50 mm.

The Clip Applier is a disposable device with a handle, shaft, suture anchors, articulation controls, and deployment loop which contains the Clip. This Special 510(k) contains design modifications to the predicate AtriClip LAA Exclusion System (PRO1) intended to eliminate the End Effector Hoop configuration, allow for active articulation via articulation controls, and increase ease of deployment of the clip.

V. Indications For Use

The AtriClip LAA Exclusion System is indicated for the occlusion of the left atrial appendage, under direct visualization, in conjunction with other open cardiac surgical procedures.

Direct visualization, in this context, requires that the surgeon is able to see the heart directly, without assistance from a camera, endoscope, etc., or any other viewing technology. This includes procedures performed by sternotomy (full or partial) as well as thoracotomy (single or multiple).

VI. Comparison Of Technological Characteristics With The Predicate Device

- The devices have the same intended use, and;
- No changes were made in operating principle, or specifications of performance, and;
- Both the PRO1 and PRO2 Appliers use the Gillinov-Cosgrove Clip, and;
- Both the predicate and proposed device are made of similar patient contacting materials (medical grade metals and plastics) with long and safe histories of use.
- The results of the verification and validation testing:
    - Demonstrated equivalency in performance
    - Device biocompatibility remains unchanged
    - Did not raise any new issues of safety

The modifications to the proposed AtriClip LAA Exclusion System are intended to eliminate the existing End Effector Hoop configuration, allow for active articulation via articulation controls, and to increase ease of deployment.

VII. Performance Data

<u>Non-clinical Bench Testing</u>

- Mechanical Testing
- Reliability Testing
- Magnetic Resonance Testing – Per FDA Guidance (December 11, 2014) Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment
- Bench Testing on an Animal Model

Biocompatibility Testing

The biocompatibility evaluation for the PRO2 clip applier was conducted in accordance with the International Standard ISO 10993-1 “Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process” as recognized by FDA. The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation
- Systemic Toxicity
- Material Mediated Pyrogen

The PRO2 clip applier is categorized as an “External Communicating Device,” contact for “Tissue/Bone” and contact duration for “under 24 hours.”

VIII. Conclusions

The modified AtriClip LAA Exclusion System (PRO2) is equivalent to the previously cleared AtriClip LAA Exclusion System (PRO1) as there is no change to intended use, operating principals, or function of the device.