DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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May 19, 2017

AtriCure Inc.
Jonathan McElwee
Regulatory Affairs Manger
7555 Innovation Way
Mason, Ohio 45040

Re: K163261
Trade/Device Name: AtriClip Pro, Pro2, and Pro V LAA Exclusion Systems With Preloaded Gillinov-Cosgrove Clip
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable Clip
Regulatory Class: Class II
Product Code: FZP
Dated: April 19, 2017
Received: April 20, 2017

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,

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)*
K163261

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, performed under direct visualization and in conjunction with other cardiac surgical procedures.
Direct visualization, in this context, requires that the surgeon is able to see the heart directly, with or without assistance from a camera, endoscope, etc., or other appropriate viewing technologies.

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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AtriCure®

510(k) Summary

I. Submitter

Manufacturer: AtriCure, Inc.
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Contact Person: Jonathan McElwee, RAC
Regulatory Affairs Manager

Date Submitted: 11/18/2016

II. Device

Name of Devices: AtriClip LAA Exclusion System with preloaded Gillinov-Cosgrove® Clip

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

Predicate Device:
K093679 AtriClip LAA Exclusion System with Preloaded Gillinov-Cosgrove Clip

The following reference devices were also used in this submission:

- K122276 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
- K160454 AtriClip LAA Exclusion System with Preloaded Gillinov-Cosgrove Clip

IV. Device Description

The AtriClip 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 Appliers are disposable devices with a handle, shaft, suture anchors, articulation controls, and deployment end-effector containing the Clip.

V. Indications For Use

The AtriClip LAA Exclusion System is indicated for the occlusion of the heart's left atrial appendage, performed under direct visualization and in conjunction with other cardiac surgical procedures.
Direct visualization, in this context, requires that the surgeon is able to see the heart directly, with or without assistance from a camera, endoscope, etc., or other appropriate viewing technologies.

VI. Comparison Of Technological Characteristics With The Predicate Device

The AtriClip LAA Exclusion System devices have the following similarities to the technological characteristics of the previously cleared devices.

- The devices have the same intended use – "occlusion of the heart's left atrial appendage"
- Same operating principle
- Same fundamental scientific technology
- Same device designs
- Same materials used
- The results of the verification and validation testing:
    - Demonstrated equivalency in performance
    - Did not raise any new issues of safety

VII. Performance Data

Non-clinical Bench Testing
Reliability Testing
Usability Testing on a Cadaver Model

Clinical Studies
AtriCure has collected scientific based evidence from multiple sponsored IDE clinical studies on the use of the AtriClip LAA Exclusion System during video assisted thoracoscopic procedures of the left atrial appendage (LAA). In the IDE Stroke clinical study (G110145) patients were implanted with the AtriClip device via video assisted thoracoscopic procedures without any adverse events. At three months follow-up, these patients had 100% LAA exclusion.

In addition, AtriCure also conducted two IDE studies, Hybrid DEEP (G090279) and Staged DEEP (G120056), where the AtriClip devices were implanted via using video without any adverse events.

Furthermore, AtriCure performed a published literature review evaluating the use of AtriClip LAA Exclusion System devices, which provided additional evidence the device can be placed safely at the base of the appendage via a video assisted thoracoscopic procedure of the LAA.

In totality of the clinical evidence based on the multiple IDE clinical studies and published clinical literature, 129 total patients were safely implanted during video assisted thoracoscopic procedures of the left atrial appendage.

A review of the IDE clinical studies and published literature evaluated the following endpoints when the Clip was deployed via a video assisted thoracoscopic procedures of the LAA: 1.) LAA occlusion directly following Clip deployment and 2.) LAA exclusion post-operatively. The results demonstrated: 1.) 99% (128/129) of the patients had LAA occlusion directly following Clip deployment and 2.) 96% (56/58) of patients had LAA exclusion evaluated at 3-12months post-operatively.

The IDE EXCLUDE clinical study, included in the original AtriClip 510(k) premarket notification - K093679, demonstrated effectiveness of 95.7% LAA occlusion directly following Clip deployment and 98.4% LAA exclusion 3 months post-operatively.

There were Zero (0) AtriClip device related serious adverse events reported in the clinical studies and published literature.

Summary
Based on the clinical performance as documented in the clinical studies and published literature, the AtriClip LAA Exclusion System was found to have a safety and effectiveness profile similar to the predicate device. Substantial equivalence was based in part on this information.

VIII. Conclusions

The AtriCure sponsored clinical studies, published literature, and bench testing data included in this submission provide evidence demonstrating the AtriClip LAA Exclusion System, as labeled per the Indication for Use, provide A.) clinically significant results and at the same time B.) do not present an unreasonable risk of illness or injury associated with the use of the device.