June 28, 2018

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

Re: K181474
Trade/Device Name: AtriClip LAA Exclusion System
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable Clip
Regulatory Class: Class II
Product Code: PZX
Dated: June 1, 2018
Received: June 4, 2018

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.

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,

Rachel E. Neubrander -S

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181474

Device Name
AtriClip LAA Exclusion System

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.

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

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AtriCure®

510(k) Summary

I. Applicant Information

Manufacturer: AtriCure, Inc.
7555 Innovation Way
Mason, OH 45040
P: 513-755-4100
F: 513-755-4108

Contact Person: Jonathan McElwee
Manager of Regulatory Affairs

Date Prepared: 05/31/2018

II. Device Information

Name of Device: AtriClip® LAA Exclusion System

Common Name: Implantable Clip and Clip Applier

Classification Name: Implantable Clip and Clip Applier (21 CFR 878.4300)
Class II
Product Code: PZX
Classification Panel: General and Plastic Surgery

Predicate Device: The device proposed for modification in this submission is the AtriClip LAA Exclusion System cleared via K180010 on January 31, 2018.

The following reference devices were also used in this submission:

- K093679 AtriClip LAA Exclusion System
- K122276 AtriClip LAA Exclusion System
- K131107 AtriClip LAA Exclusion System
- K142120 AtriClip LAA Exclusion System
- K150996 AtriClip LAA Exclusion System
- K153500 AtriClip LAA Exclusion System
- K160454 AtriClip LAA Exclusion System
- K163261 AtriClip LAA Exclusion System
- K172742 AtriClip LAA Exclusion System
- K173031 AtriClip LAA Exclusion System

III. Device Description

The 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 device with a handle, shaft, suture anchors, articulation controls, and deployment loop which contains the Clip. This Special 510(k) contains an alternate to the PET suture supply sourcing used within the AtriClip implant and Clip Appliers of the LAA Exclusion system.

IV. 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 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 any other viewing technologies.

V. 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.
- The contraindications, warnings, and precautions remain the same
- The results of the verification and validation testing:
    - Demonstrated equivalency in performance
    - Device biocompatibility remains unchanged
    - Did not raise any new issues of safety

VI. Performance Data

The following bench testing was conducted for design and performance elements deemed appropriate to demonstrate equivalence to the previously cleared AtriClip LAA Exclusion System

Non-clinical Bench Testing

- Tensile Testing (Strength, Knotted Strength)
- Suture Elongation
- Friction Comparison Testing

Biocompatibility Testing

The biocompatibility evaluation for the AtriClip LAA Exclusion System with Preloaded Gillinov-Cosgrove Clip AOD1, and PROV Clip, AOD2 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:

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

VII. Conclusions

AtriCure has demonstrated that the modifications made to the AtriClip LAA Exclusion System is equivalent to the previously cleared AtriClip LAA Exclusion System as there is no change to intended use, operating principals, or function of the device.