January 31, 2018

AtriCure, Inc.
Brittany Lowe
Regulatory Affairs Specialist
7555 Innovation Way
Mason, Ohio 45040

Re: K180010
Trade/Device Name: AtriClip FLEX-V
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable Clip
Regulatory Class: Class II
Product Code: FZP
Dated: December 29, 2017
Received: January 2, 2018

Dear Ms. Lowe:

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Nicole G. Ibrahim -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)*
K180010

Device Name
AtriClip FLEX-V

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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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: Brittany Lowe
Regulatory Affairs Specialist

Alternate Contact: Jonathan McElwee, RAC
Manager, Regulatory Affairs

Date Prepared: 1/31/2018

II. Device Information

Proprietary Name: AtriClip FLEX·V™ device

Common Name: Implantable Clip and Clip Applier

Classification: Implantable Clip and Clip Applier
Regulatory Class: Class II; per 21 CFR 878.4300
Product Code: FZP
Classification Panel: General and Plastic Surgery

Predicate Device: AtriClip LAA Exclusion System with Preloaded PRO·V Clip (K173031, FZP, October 25, 2017)

III. Device Description

The AtriClip FLEX·V device 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 AtriClip FLEX·V device is a disposable device with a handle, shaft, suture anchors, shaft rotation knob, and deployment end-effector containing the Clip.

IV. Intended Use/ 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.

V. Comparison of Technological Characteristics (PRO·V cleared via K173031)

The AtriClip system is comprised of an implantable Clip and the Clip Applier used to deliver the clip to the implant site. The implantable Clip used in the subject device and predicate device are identical. Modifications were made to the Clip Applier design only, to accommodate differing body habitus and surgeon preference. These changes include:

- Addition of an aluminum shaft for malleability
- An end effector that can be manually rotated 180° in 45° increments for physician preference and patient anatomy
- A one handed trigger to deploy the clip
- An over-center feature to reduce the force needed to hold the clip open
- A pistol grip style handle for physician preference

The intended use, operating principles, performance specifications, sterilization and expiration dating of the subject device are the same as the predicate device.

VI. Performance Data

The following bench testing was conducted for design and performance elements deemed appropriate to demonstrate equivalence to the previously cleared PRO·V device. The AtriClip FLEX·V device met the predetermined acceptance criteria ensuring substantial equivalence to the previously cleared PRO·V device. No new safety or performance issues were raising during testing.

Non-clinical Bench Testing:

- Reliability Testing
- Mechanical Testing
- Drop Testing
- Biocompatibility Testing
- Transit Testing
- Shelf Life Testing

VII. Conclusions

AtriCure has demonstrated that the modifications made to the AtriClip FLEX·V device are substantially equivalent in fundamental design, technology, function, device materials, packaging, sterilization, operating principal, and intended use/ indication for use as the previously cleared device: AtriClip LAA Exclusion System with Preloaded PRO·V Clip.