DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 28, 2014

AtriCure, Inc.
Jonathan McElwee
Regulatory Engineer
6217 Centre Park Drive
West Chester, OH 45069

Re: K142120
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: August 1, 2014
Received: August 4, 2014

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" (21CFR 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

Indications for Use

510(k) Number (if known) K142120

Device Name: AtriClip LAA Exclusion System

Indications for Use:

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).

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CRF 801 Subpart D) (21 CRF 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

I. Submitter

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

Contact Person: Jonathan McElwee, RAC
Regulatory Engineer

Date Prepared: 08/01/2014

II. Device

Name of Device: AtriClip™ LAA Exclusion System with preloaded Gillinov-Cosgrove Clip (ACH235, ACH240, ACH245, ACH250)

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 with Preloaded Gillinov-Cosgrove Clip cleared via 510(k) K093679 on June 10, 2010, K122276 on August 29, 2012, and K131107 on May 14, 2013.

The predicate devices have not been subject to a design-related recall.

No reference devices were used in this submission.

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. 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 available in the following lengths to accommodate different sizes of LAA: 35 mm, 40 mm, 45 mm, and 50 mm. This Special 510(k) does not include any changes to the Clip.

The Clip Applier is a disposable device with a handle, shaft, suture anchors, and deployment loop which contains the Clip. This Special 510(k) includes modifications to the Clip Applier including a malleable aluminum alloy shaft.

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;
- The devices use the same pre-loaded Gillinov-Cosgrove Clip.
- The basic design of the proposed device and the previously cleared devices are the same. The devices are disposable, single-use instruments including a handle, malleable shaft, suture anchors, and deployment loop containing the Clip.
- The modifications to the proposed AtriClip Applier are designed to provide increased options for surgeons based on patient body habitus and surgeon preference. Major modifications compared to the predicate include the ability to bend the shaft in all directions.

VII. Performance Data

The modified Clip Applier was tested on an animal model to confirm the modifications do not affect the ability to successfully deploy the Clip on the left atrial appendage. Additional testing per 21 CFR 820.30 and AtriCure's Quality System was performed to verify the modified Clip Applier's conformance to design controls and specification. Testing determined that the modified Clip Applier was able to successfully deploy the Clip on the LAA and that the modified Clip Applier conformed to design controls and product specifications.

Non-clinical Bench Testing

- Mechanical Testing
- Reliability Testing
- Deployment Testing on an Animal Model
- Transit Testing

VIII. Conclusions

The modified AtriClip LAA Exclusion System is equivalent to the previously cleared AtriClip LAA Exclusion System as there is no change to intended use, the implant Gillinov-Cosgrove Clip, or the basic design of the Clip Applier. The modifications to the Clip Applier do not affect the ability of the Clip to be successfully deployment on the LAA.