August 21, 2019

AtriCure, Inc
Jim Taufen
Sr. Manager, Regulatory Affairs
7555 Innovation Way
Mason, Ohio 45040

Re: K191413
Trade/Device Name: AtriClip LAA Exclusion System with preloaded Gillinov-Cosgrove Clip, AtriClip LAA Exclusion System with preloaded V-Clip
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable Clip
Regulatory Class: Class II
Product Code: PZX
Dated: May 24, 2019
Received: May 28, 2019

Dear Mr. Taufen:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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 Neubrander, Ph.D.
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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)*
K191413

Device Name
AtriClip LAA Exclusion System

Indications for Use *(Describe)*
The AtriClip LAA Exclusion System is indicated for the exclusion 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.
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Mason, OH 45040
P: (952) 314-1507
F: (513) 755-4108

Contact Person: Jim M. Taufen
Senior Manager, Regulatory Affairs

Date Prepared: August 20, 2019

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 K181474 on June 28, 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
- K160454 AtriClip LAA Exclusion System
- K153500 AtriClip LAA Exclusion System
- K163261 AtriClip LAA Exclusion System
- K172742 AtriClip LAA Exclusion System
- K173031 AtriClip LAA Exclusion System
- K180010 AtriClip LAA Exclusion System
- K181474 AtriClip LAA Exclusion System

III. Device Description

The AtriClip Exclusion System contains a clip for exclusion of the heart's left atrial appendage (LAA). Preclinical animal studies (Kamohara 2005, 2006) demonstrate that complete exclusion with the Clip also results in acute and chronic electrical isolation of the LAA. A human clinical study (Starck 2012) has demonstrated acute electrical isolation. Chronic electrical isolation has not been evaluated in human clinical studies. The Clip is pre-loaded on a disposable Clip applier. The AtriClip Exclusion System does not contain natural rubber latex components.

IV. Indications For Use

The AtriClip LAA Exclusion System is indicated for the exclusion 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

AtriCure updated the LAA Exclusion System indications and device description in the instructions for use labeling. A comparison of the technological characteristics with the predicate device are provided in **Table 1** below.

Table 1: Comparison of Technological Characteristics

Feature	Predicate (K181474) AtriClip™ LAA Exclusion System	Subject AtriClip™ LAA Exclusion System	Equivalence Comparison
Proprietary Name	AtriClip LAA Exclusion System with Preloaded Gillinov-Cosgrove Clip AtriClip® LAA Exclusion System with preloaded V-Clip	AtriClip LAA Exclusion System with Preloaded Gillinov-Cosgrove Clip AtriClip® LAA Exclusion System with preloaded V-Clip	n/a
Model Numbers	LAA035 LAA040 LAA045 LAA050 ACH135 ACH140 ACH145 ACH150 ACH235 ACH240 ACH245 ACH250 PRO135 PRO140 PRO145 PRO150 PRO235 PRO240 PRO245 PRO250 ACHV35 ACH40 ACHV45 ACHV50 PROV35 PROV40 PROV45 PROV50	LAA035 LAA040 LAA045 LAA050 ACH135 ACH140 ACH145 ACH150 ACH235 ACH240 ACH245 ACH250 PRO135 PRO140 PRO145 PRO150 PRO235 PRO240 PRO245 PRO250 ACHV35 ACH40 ACHV45 ACHV50 PROV35 PROV40 PROV45 PROV50	n/a
Indications for Use	The AtriClip LAA Exclusion System is indicated for the occlusion of the heart's left atrial appendage, performed	The AtriClip LAA Exclusion System is indicated for the exclusion of the heart's left atrial appendage, performed under direct	Similar. AtriClip devices have

Feature	Predicate (K181474) AtriClip™ LAA Exclusion System	Subject AtriClip™ LAA Exclusion System	Equivalence Comparison
	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.	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.	the same intended use
Device Description in the Instructions for Use	The AtriClip LAA Exclusion System contains the Gillinov-Cosgrove LAA Clip (Clip) for occlusion of the heart's left atrial appendage (LAA). The Clip is pre-loaded on a disposable Clip applier. The AtriClip LAA Exclusion System with preloaded Gillinov-Cosgrove Clip does not contain natural rubber latex component.	The AtriClip LAA Exclusion System contains {*Clip Type} LAA Clip (Clip) for exclusion of the heart's left atrial appendage (LAA). Preclinical animal studies (Kamohara 2005, 2006) demonstrate that complete exclusion with the Clip also results in acute and chronic electrical isolation of the LAA. A human clinical study (Starck 2012) has demonstrated acute electrical isolation. Chronic electrical isolation has not been evaluated in human clinical studies. The Clip is pre-loaded on a disposable Clip applier. The AtriClip LAA Exclusion System with preloaded {*Clip Type} Clip does not contain natural rubber latex component. * AOD1: "Gillinov-Cosgrove" * AOD2: "V"	Different. AtriClip devices have the same intended use
Preloaded Clip	**AOD1:** Preloaded Gillinov-Cosgrove Clip **AOD2:** Preloaded V-Clip	**AOD1:** Preloaded Gillinov-Cosgrove Clip **AOD2:** Preloaded V-Clip	Same
Shelf Life	3 years	3 years	Same
Biocompatibility	Passed. Materials have been assessed based on ISO 10993 and are commonly employed in tissue contacting devices	Passed. Materials have been assessed based on ISO 10993 and are commonly employed in tissue contacting devices	Same
Sterilization	Gamma Irradiation.	Gamma Irradiation.	Same

Feature	Predicate (K181474) AtriClip™ LAA Exclusion System	Subject AtriClip™ LAA Exclusion System	Equivalence Comparison
Sterility Assurance Level	10^{-6} SAL	10^{-6} SAL	Same

The proposed changes in the indications for use statement and instruction for use were supported by published animal and clinical data. The proposed changes do not include any change to intended use, contraindications, or precautions. Additional warnings have been added to the labeling:

Warning:

- The safety and effectiveness of this device in atrial rhythm control management, either alone or in combination with ablative treatment, has not been established.
- AtriClip placement that allows blood flow into the LAA may not result in complete exclusion and/or electrical isolation.

The proposed changes have no impact on design, operating principles, performance specifications, packaging, sterilization or expiring dating.

VI. Performance Data

The proposed changes do not include any change to design or performance specifications of the AtriClip LAA Exclusion System. Additionally, the proposed changes did not modify the intended use, therefore the previously submitted bench and animal data remain valid for the AtriClip LAA Exclusion System.

VII. Conclusions

A review of the risk analysis concluded there is no overall change to the risk profile of the proposed AtriClip LAA Exclusion System versus the previously cleared AtriClip LAA Exclusion System as the modifications to the proposed AtriClip LAA Exclusion System IFU do not add or remove any features of the device or change the clinical application. AtriCure has demonstrated that the AtriClip LAA Exclusion System IFU, as labeled per the proposed Indication for Use and IFU description section, is substantially equivalent to the predicate LAA Exclusion System (K181474) as there is no change to intended use, operating principals, or function of the device.