March 3, 2021

AtriCure, Inc.
Mary Galeano
Senior Regulatory Affairs Specialist
7555 Innovation Way
Mason, Ohio 45040

Re: K210293
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: January 29, 2021
Received: February 2, 2021

Dear Mary Galeano:

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
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)*
K210293

Device Name
AtriClip LAA Exclusion System with preloaded Gillinov-Cosgrove Clip, AtriClip LAA Exclusion System with preloaded V-Clip

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.
7555 Innovation Way
Mason, Ohio 45040

Contact Person: Mary Galeano, RAC
Sr. Regulatory Affairs Specialist
P: 513-257-6279

Alternate Contact: Jonathan McElwee, RAC
Sr. Manager, Regulatory Affairs
P: 513-795-9127

Date Prepared: 03/03/2021

II. Device Information

Proprietary Name: AtriClip™ LAA Exclusion System with preloaded Gillinov-Cosgrove Clip
(LAA0, ACH1, ACH2, PRO1, and PRO2)
AtriClip™ LAA Exclusion System with preloaded V-Clip
(PROV and ACHV)

Common Name: Implantable Clip and Clip Applier

Classification: Implantable Clip and Clip Applier
Regulatory Class: Class II; per 21 CFR 878.4300
Product Code: PZX
Classification Panel: Cardiovascular

Predicate Device: The device proposed for modification in this submission is the AtriClip LAA Exclusion System cleared via K191413 on August 21, 2019.

III. 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 exclusion of the 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 available in the following lengths to accommodate difference 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.

Intended Use/ Indications for Use

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.

IV. Comparison of Technological Characteristics with the Predicate Device (AtriClip LAA Exclusion System - K191413)

AtriCure added an alternate raw material supplier of the titanium for the AOD1 clip.

#	Feature	Previously Cleared AtriClip™ LAA Exclusion System	Modified AtriClip™ LAA Exclusion System	Equivalence Comparison
1	Proprietary Name	**AOD1:** AtriClip LAA Exclusion System with Preloaded Gillinov-Cosgrove Clip **AOD2:** AtriClip LAA Exclusion System with Preloaded PROV Clip	**AOD1:** AtriClip LAA Exclusion System with Preloaded Gillinov-Cosgrove Clip **AOD2:** AtriClip LAA Exclusion System with PROV Clip	Same
2	Clip Applier Product Code(s)	LAA035 LAA040 LAA045 LAA050 ACH135 ACH140 ACH145 ACH150 ACH235 ACH240 ACH245 ACH250 PRO135 PRO140 PRO145 PRO150 PRO235 PRO240 PRO245 PRO250 ACHV35 ACHV40 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 ACHV40 ACHV45 ACHV50 PROV35 PROV40 PROV45 PROV50	Same
3	Device Classification	21 CFR 878.4300, product code: PZX	21 CFR 878.4300, product code: PZX	Same
4	Regulatory Class	Class II	Class II	Same
5	FDA Division	Cardiovascular	Cardiovascular	Same
6	Performance Standards	No performance standards applicable to this product have been promulgated by FDA	No performance standards applicable to this product have been promulgated by FDA	Same
7	Intended Use	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.	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.	Same

#	Feature	Previously Cleared AtriClip™ LAA Exclusion System	Modified AtriClip™ LAA Exclusion System	Equivalence Comparison
8	Device Description in the Instructions for Use	The AtriClip LAA Exclusion System contains the Gillinov-Cosgrove 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 Gillinov-Cosgrove Clip does not contain natural rubber latex components.	The AtriClip LAA Exclusion System contains the Gillinov-Cosgrove 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 Gillinov-Cosgrove Clip does not contain natural rubber latex components.	Same
9	Software	This product does not contain software.	This product does not contain software.	Same
10	Shelf Life	3 years.	3 years.	Same
11	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
12	Sterilization	Gamma Irradiation.	Gamma Irradiation.	Same
13	Sterility Assurance Level	10^{-6} SAL	10^{-6} SAL	Same
14	Pyrogen	Non-Pyrogenic.	Non-Pyrogenic.	Same
Clip				
15	Suture Material	Polyethylene Terephthalate	Polyethylene Terephthalate	Same
16	Preloaded Clip	**AOD1:** Preloaded Gillinov-Cosgrove Clip **AOD2:** Preloaded V-Clip	**AOD1:** Preloaded Gillinov-Cosgrove Clip **AOD2:** Preloaded V-Clip	Same
17	Clip Opening	**AOD1:** Opens 12.5mm ± 1.5mm as measured between the beams of the AOD1 clip. **AOD2:** Opens AOD2 Clip to a minimum of 12mm at the distal end and 4mm at the proximal end of the clip.	**AOD1:** Opens 12.5mm ± 1.5mm as measured between the beams of the AOD1 clip. **AOD2:** Opens AOD2 Clip to a minimum of 12mm at the distal end and 4mm at the proximal end of the clip.	Same
19	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
20	Sterilization	Gamma Irradiation.	Gamma Irradiation.	Same

- 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

V. Performance Data

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 do not add or remove any features of the device or change the clinical application.

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.

VI. Conclusions

AtriCure has demonstrated that the modifications made to the AtriClip LAA Exclusion System are substantially equivalent in fundamental design, technology, function, device materials, packaging, sterilization, operating principle, and intended use / indication for use as the previously cleared AtriClip LAA Exclusion System) per K191413.