November 2, 2023

AtriCure, Inc.
Stephanie Hadnot
Senior Regulatory Affairs Specialist
7555 Innovation Way
Mason, Ohio 45040

Re: K233407
Trade/Device Name: AtriClip® LAA Exclusion System with Preloaded Gillinov-Cosgrove® Clip (LAA0, ACH1, ACH2, PRO1, and PRO2)
AtriClip® PRO-V® LAA Exclusion System (PROV)
AtriClip® Flex-V® LAA Exclusion System with Preloaded V Clip™ (ACHV)

Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable Clip
Regulatory Class: Class II
Product Code: PZX
Dated: September 29, 2023
Received: October 5, 2023

Dear Stephanie Hadnot:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Katherine N. Trivedi
-S

for 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K233407

Device Name
AtriClip® LAA Exclusion System with Preloaded Gillinov-Cosgrove® Clip (LAA0, ACH1, ACH2, PRO1, and PRO2)
AtriClip® PRO-V® LAA Exclusion System (PROV)
AtriClip® Flex-V® LAA Exclusion System with Preloaded V Clip™ (ACHV)

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: Stephanie Hadnot
Senior Regulatory Affairs Specialist
P: 513-341-0345

Alternate Contact: Jim Taufen
Director, Regulatory Affairs
P: 952-314-1507

Date Prepared: 09/29/2023

II. Device Information

Proprietary Name: AtriClip® LAA Exclusion System with Preloaded Gillinov-Cosgrove® Clip
(LAA0, ACH1, ACH2, PRO1, and PRO2)
AtriClip® PRO-V® LAA Exclusion System (PROV)
AtriClip® Flex-V® LAA Exclusion System with Preloaded V Clip™ (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 K210293 on March 3, 2021.

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). The Clip is then deployed and is left as a permanent implant and excludes the LAA resulting in electrical isolation of the 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 devices with a handle, shaft, suture anchors, articulation controls, and deployment loop/jaws which contain 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.

The indications for use are identical to the predicate device.

IV. Comparison of Technological Characteristics with the Predicate Device (AtriClip LAA Exclusion System – K210293)

#	Feature	Predicate (K210293) 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 V Clip	**AOD1:** AtriClip LAA Exclusion System with Preloaded Gillinov-Cosgrove Clip **AOD2:** AtriClip LAA Exclusion System with Preloaded V 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 PROV35, PROV40, PROV45, PROV50 ACHV35, ACHV40, ACHV45, ACHV50	LAA035, LAA040, LAA045, LAA050 ACH135, ACH140, ACH145, ACH150 ACH235, ACH240, ACH245, ACH250 PRO135, PRO140, PRO145, PRO150 PRO235, PRO240, PRO245, PRO250 PROV35, PROV40, PROV45, PROV50 ACHV35, ACHV40, ACHV45, ACHV50	Same
3	Selection Guide Product Code	CGG100	CGG100	Same
4	Device Classification	21 CFR 878.4300, product code: PZX	21 CFR 878.4300, product code: PZX	Same
5	Regulatory Class	Class II	Class II	Same
6	FDA Division	Cardiovascular	Cardiovascular	Same
7	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
8	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 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	Same

#	Feature	Predicate (K210293) AtriClip™ LAA Exclusion System	Modified AtriClip™ LAA Exclusion System	Equivalence Comparison
		the heart directly, with or without assistance from a camera, endoscope, etc., or other appropriate viewing technologies.	the heart directly, with or without assistance from a camera, endoscope, etc., or other appropriate viewing technologies.	
9	Contraindications	LAA0, ACH1, ACH2, PRO1, PRO2: 1. Do not use this device as a contraceptive tubal occlusion device. 2. Do not use this device if the patient has a known allergy to Nitinol (nickel titanium alloy). PROV, ACHV: 1. Do not use this device as a contraceptive tubal occlusion device.	LAA0, ACH1, ACH2, PRO1, PRO2: 1. Do not use this device as a contraceptive tubal occlusion device. 2. Do not use this device if the patient has a known allergy to Nitinol (nickel titanium alloy). 3. Do not use this device if evidence of systemic infection, bacterial endocarditis, or in presence of infected operating field. PROV, ACHV: 1. Do not use this device as a contraceptive tubal occlusion device. 2. Do not use this device if evidence of systemic infection, bacterial endocarditis, or in presence of infected operating field.	Similar – Contraindication added to emphasize standard surgical practice and possible limited use of devices.
10	Software	This product does not contain software.	This product does not contain software.	Same
11	Shelf Life	3 years	3 years	Same
12	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
13	Sterilization	Gamma Irradiation	Gamma Irradiation	Same
14	Sterility Assurance Level	10^{-6} SAL	10^{-6} SAL	Same
15	Pyrogen	Non-Pyrogenic	Non-Pyrogenic	Same
Clip				
16	Suture Material	Polyethylene Terephthalate	Polyethylene Terephthalate	Same
17	Preloaded Clip	**AOD1:** Preloaded Gillinov-Cosgrove Clip **AOD2:** Preloaded V Clip	**AOD1:** Preloaded Gillinov-Cosgrove Clip **AOD2:** Preloaded V Clip	Same
18	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.
- No changes were made in operating principle.
- No changes to the overall design or function of the devices.

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.

V. 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 K210293.
