January 15, 2025

AtriCure, Inc.
Diane Sung
Senior Regulatory Affairs Specialist
7555 Innovation Way
Mason, Ohio 45040

Re: K243860
Trade/Device Name: AtriClip PRO-Mini LAA Exclusion System (PROM)
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: Class II
Product Code: PZX
Dated: December 16, 2024
Received: December 16, 2024

Dear Diane Sung:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Kalkidan Molla -S

Kalkidan A. Molla, MS
Acting 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243860

Device Name
AtriClip PRO-Mini LAA Exclusion System (PROM)

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

Applicant Information

Manufacturer: AtriCure, Inc.
7555 Innovation Way
Mason Ohio 45040

Contact Person: Diane Sung
Senior Regulatory Affairs Specialist
P: 513-600-1804

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

Date Prepared: December 16, 2024

Device Information

Proprietary Name: AtriClip PRO-Mini LAA Exclusion System (PROM)

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: AtriClip FLEX-Mini LAA Exclusion System (ACHM) (K234125, July 29, 2024)

Reference Device: AtriClip LAA Exclusion System with Preloaded Gillinov-Cosgrove Clip (PRO2) (K160454, March 18, 2016, and K172742, October 11, 2017)

Device Description

The AtriClip PRO-Mini LAA Exclusion System consists of a single use, sterile, self-closing, implantable Clip (AtriClip Mini) 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. The Clip is available in the following lengths to accommodate different sizes of LAA: 35 mm, 40 mm, 45 mm, and 50 mm. The PRO-Mini device is a disposable device with a handle, left/right and up/down articulation knobs, articulation lock, deployment tab, shaft, suture anchors, and end effector containing the AtriClip Mini.

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.

Comparison of Technological Characteristics

- The devices include the same intended use and indications for use, and;
- No changes were made in operating principle, and;
- The results of the verification and validation testing:
  - Demonstrated equivalency in performance
  - Did not raise any new issues of safety

#	Feature	AtriClip FLEX-Mini LAA Exclusion System with AtriClip Mini (ACHM) (Predicate) K234125	AtriClip LAA Exclusion System with Preloaded Gillinov-Cosgrove LAA Clip (PRO2) (Reference) K160454, K172742	PRO-Mini (PROM) (Proposed)	Equivalence Comparison
1	Proprietary Name	AtriClip FLEX-Mini LAA Exclusion System	AtriClip LAA Exclusion System with Preloaded Gillinov-Cosgrove Clip	AtriClip PRO-Mini LAA Exclusion System	N/A
2	Product Code(s)	ACHM35 ACHM40 ACHM45 ACHM50	PRO235 PRO240 PRO245 PRO250	PROM35 PROM40 PROM45 PROM50	N/A
3	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,	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,	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,	Same as predicate and reference devices.

		with or without assistance from a camera, endoscope, etc., or other appropriate viewing technologies.	with or without assistance from a camera, endoscope, etc., or other appropriate viewing technologies.	with or without assistance from a camera, endoscope, etc., or other appropriate viewing technologies.	
4	Packaging	Sterile, Single use, disposable device	Sterile, Single use, disposable device	Sterile, Single use, disposable device	Same as predicate and reference devices.
5	Biocompatibility	Materials have been assessed based on ISO 10993 and are commonly employed in tissue contacting devices.	Materials have been assessed based on ISO 10993-1 and are commonly employed in tissue contacting devices.	Materials have been assessed based on ISO 10993-1 and are commonly employed in tissue contacting devices.	Same as predicate and reference devices.
6	Sterilization	Gamma Irradiation	Gamma Irradiation	Gamma Irradiation	Same as predicate and reference devices.
7	Sterility Assurance Level	10^{-6} SAL	10^{-6} SAL	10^{-6} SAL	Same as predicate and reference devices.
Clip					
8	Preloaded Clip	AtriClip Mini (AOD3)	N/A	AtriClip Mini (AOD3)	Same as predicate device.
9	Operating Mechanism	Uniform pressure along length of the Clip	N/A	Uniform pressure along length of the Clip	Same as predicate device.
10	Contact Surface	Knit Braided Polyester	N/A	Knit Braided Polyester	Same as predicate device.
Clip Applier					
11	Deployment End Effector	N/A	Stainless steel jaws that open and close, as well as provide the pathway for stainless steel cables to route and attach to the Clip.	Stainless steel jaws that open and close, as well as provide the pathway for stainless steel cables to route and attach to the Clip.	Same as reference device.
12	Shaft	N/A	Stainless Steel	Stainless Steel	Same as reference device.
13	Handle	N/A	Polycarbonate	Polycarbonate	Same as reference device.

Performance Data

The following bench testing was conducted for design and performance elements deemed appropriate to demonstrate equivalence to the previously cleared AtriClip LAA Exclusion System devices (ACHM, PRO2). The AtriClip PRO-Mini LAA Exclusion System (PROM) met the predetermined acceptance criteria ensuring substantial equivalence to the previously cleared AtriClip LAA Exclusion System devices (ACHM, PRO2). No new safety or performance issues were raised during testing.

Non-clinical Bench Testing:

- Mechanical Testing
- Reliability Testing
- Tissue Testing
- Dose Audit Testing

Conclusions

AtriCure has demonstrated that the AtriClip PRO-Mini LAA Exclusion System (PROM) is substantially equivalent in fundamental design, technology, function, device materials, packaging, sterilization, operating principle, and intended use / indication for use as the previously cleared AtriClip FLEX-Mini LAA Exclusion System (ACHM) per K234125 and AtriClip LAA Exclusion System with Preloaded Gillinov-Cosgrove Clip (PRO2) per K160454 and K172742.