October 21, 2026

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

Re: K263319
Trade/Device Name: ACHM30 AtriClip FLEX-Mini LAA Exclusion System
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: Class II
Product Code: PZX, FZX
Dated: September 21, 2026
Received: September 21, 2026

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

Katherine N. Trivedi -S
Digitally signed by Katherine N. Trivedi -S
Date: 2026.10.21 21:11:01 -06'00'

Katherine Trivedi
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)*
K263319

Device Name
ACHM30 AtriClip FLEX-Mini® 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

Applicant Information

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

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

Alternate Contact: Angie Kilian
Senior Manager, Regulatory Affairs
P: 952-994-1444

Date Prepared: September 22, 2026

Device Information

Proprietary Name: ACHM30 AtriClip FLEX-Mini LAA Exclusion System

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)

Device Description

The ACHM30 AtriClip FLEX-Mini LAA Exclusion System contains the AtriClip Mini 30 mm (AOD3 30 mm) for exclusion of the heart's left atrial appendage. The AOD3 30 mm is a self-closing, sterile, implantable clip. The AOD3 30 mm is a medical implant for exclusion of the heart's left atrial appendage (LAA) via an epicardial approach during cardiac surgery. The AOD3 30 mm is designed to atraumatically occlude the target tissue structure by approximating the walls of the heart's LAA to manually exclude and electrically isolate the LAA from the left atrium. The excluded tissue heals normally at the site of the approximation and atrophies distal to the device. The AOD3 Clip is currently available in the following lengths to accommodate different sizes of LAA: 35 mm, 40 mm, 45 mm, and 50 mm. The current submission is to add a 30 mm clip size for smaller left atrial appendages. The FLEX-Mini 30 mm device is a disposable device with a handle, shaft, suture anchors, shaft rotation knob, and end effector containing the AtriClip Mini 30 mm.

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 LAA Exclusion System with AtriClip Mini (ACHM) (Predicate) K234125	AtriClip LAA Exclusion System with AtriClip Mini - 30 mm (ACHM30) (Proposed)	Equivalence Comparison
1	Proprietary Name	AtriClip FLEX-Mini LAA Exclusion System	AtriClip FLEX-Mini LAA Exclusion System	Same
2	Product Codes	ACHM35 ACHM40 ACHM45 ACHM50	ACHM30	Similar, 1 additional product code for the proposed device with a 30mm clip.

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, 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
4	Packaging	Sterile Single use disposable device	Sterile Single use disposable device	Same
5	Shelf Life	3 Year Shelf Life	3 Year Shelf Life	Same
6	Biocompatibility	Materials have been assessed based on ISO 10993-1 and are commonly employed in implantable devices.	Materials have been assessed based on ISO 10993-1 and are commonly employed in implantable devices.	Same
7	Sterilization	Gamma Irradiation	Gamma Irradiation	Same
8	Sterility Assurance Level	10^{-6} SAL	10^{-6} SAL	Same
Clip Implant				
9	Preloaded Clip	AtriClip Mini (AOD3)	AtriClip Mini (AOD3 30 mm)	Similar - Sizing according to LAA
10	Operating Mechanism	Uniform pressure along length	Uniform pressure along length	Same
11	Contact Surface	Knit Braided Polyester	Knit Braided Polyester	Same
Clip Applier				
12	Deployment End Effector	Stainless steel jaws that open and close, as well as provide the pathway for stainless steel cables to route and attach to the Clip via sutures.	Stainless steel jaws that open and close, as well as provide the pathway for stainless steel cables to route and attach to the Clip via sutures.	Same
13	Shaft	Aluminum	Aluminum	Same
14	Handle	Polycarbonate	Polycarbonate	Same

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 device (ACHM). The AtriClip FLEX-Mini 30 mm LAA Exclusion System (ACHM30) met the predetermined acceptance criteria ensuring substantial equivalence to the previously cleared AtriClip LAA Exclusion System device (ACHM). No new safety or performance issues were raised during testing.

Non-clinical Bench Testing:

- Mechanical Testing
- Reliability Testing
- Aperture Testing

Conclusions

AtriCure has demonstrated that the AtriClip FLEX-Mini 30 mm LAA Exclusion System (ACHM30) 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.