



June 26, 2026

Edwards Lifesciences
Corinne Yestrepky
Sr. Manager Regulatory Affairs
One Edwards Way
Irvine, CA 92614 USA

Re: K254232

Trade/Device Name: ECLIPTIS Left Atrial Appendage Exclusion System
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable Clip
Regulatory Class: Class II
Product Code: PZX
Dated: May 26, 2026
Received: May 27, 2026

Dear Corinne Yestrepky:

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 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: 2026.06.26
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Katherine Trivedi
Assistant Director
DHT2B: Division of Circulatory Support,
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OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K254232

Device Name
ECLIPTIS Left Atrial Appendage Exclusion System

Indications for Use (Describe)

The ECLIPTIS left atrial appendage 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.

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510(k) Summary

510(k) Submitter:	Edwards Lifesciences LLC 1 Edwards Way Irvine, CA, 92614 800-424-3278
Contact Person:	Corinne Yestrepky, PhD Sr. Manager Regulatory Affairs Edwards Lifesciences LLC Corinne_Yestrepky@edwards.com Tel: 949-250-5095
Date of Preparation:	December 29, 2025
Trade Name:	ECLIPTIS Left Atrial Appendage Exclusion System
Common Name:	Implantable left atrial appendage clip and delivery system
Classification:	Regulation: 21 CFR 878.4300, implantable clip Device Class: II Product Code: PZX (Left Atrial Appendage Clip, Implantable)
Predicate Device:	AtriCure AtriClip LAA Exclusion System, K210293
Device Description:	The ECLIPTIS left atrial appendage exclusion system is an implantable clip pre-loaded onto a sterile, single-use delivery system. The clip is available in four sizes: 35, 40, 45, and 50 mm. The delivery system has a malleable shaft and rotation knob to enable access to the base of the left atrial appendage. The lever facilitates opening and closing of the clip. Once the clip is in position, it is released by pulling the red trigger and sliding the delivery system off of the clip. The delivery system can be used to recapture and redeploy the clip.
Indications for Use:	The ECLIPTIS left atrial appendage 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.

Technological Characteristics and Basis for Substantial Equivalence

The subject and predicate device share the same intended use and operating principle. A comparison of the technological characteristics of the subject and the predicate device is summarized in Table 1.

Table 1 Comparison of Technological Characteristics			
Technological Characteristic	Subject Device: ECLIPTIS Left Atrial Appendage Exclusion System	Predicate Device: AtriCure AtriClip LAA Exclusion System (K210293)	Substantial Equivalence Discussion
Indications for Use	The device 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	N/A
Device Classification	21 CFR 878.4300; Class II; Product Code: PZX (Left Atrial Appendage Clip, Implantable)	Same	N/A
Contraindications	Do not use this device as a contraceptive tubal occlusion device. Do not use this device if the patient has a known allergy to nitinol (nickel titanium alloy).	Same	N/A
Clip Sizes Offered	35 , 40 , 45 , and 50 mm	Same	N/A
Clip Mechanics	Curved mechanical clip with U-shape opening and tip-first closure. Constructed of nitinol spring, polyether ether ketone bars with silicone overmold.	Straight mechanical clip with closed loop design or V-shape opening and tip-first closure. Constructed of titanium with or without nitinol springs and covered in polyethylene terephthalate fabric – dependent on device model.	Difference in clip design does not raise new questions of safety and effectiveness. Bench and in vivo evaluations confirm subject device clip meets the intended use.
Clip to delivery system interface	Delivery system is pre-loaded with clip.	Same	N/A
Adjustment prior to deployment	Malleable shaft and rotation knob	Same	N/A

Table 1 Comparison of Technological Characteristics			
Technological Characteristic	Subject Device: ECLIPTIS Left Atrial Appendage Exclusion System	Predicate Device: AtriCure AtriClip LAA Exclusion System (K210293)	Substantial Equivalence Discussion
Adjustment after deployment	The clip is recapturable using the same delivery system. The clip can be re-deployed after recapture.	Not available.	The subject device clip can be recaptured to mitigate risks from suboptimal placement.
MR Safety	MR Conditional	Same	N/A
Biocompatibility	Materials have been assessed based on ISO 10993 and are commonly employed in tissue contacting devices and permanent implants.	Same	N/A
Pyrogen	Non-Pyrogenic	Same	N/A
Sterilization	Provided sterile for single use. Sterilized via radiation.	Same	N/A

Performance Data

Design verification and validation were performed to ensure that the subject device meets its performance specifications and demonstrates substantial equivalence to the predicate device. There are no known performance standards for this device. The following tests were conducted to demonstrate equivalence to the predicate device:

- Mechanical Testing
- Corrosion and Fatigue Testing
- Magnetic Resonance Testing
- Pyrogenicity
- Particulate Characterization
- Sterility
- Animal Study

Biocompatibility Testing

Biocompatibility of the subject device followed ISO 10993 and FDA Guidance, Use of International Standard ISO 10993-1 “Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process” dated September 8, 2023. The subject device clip is a permanent implant (contact duration > 30 days) and the subject device delivery system has limited contact (≤ 24 hours), biocompatibility endpoints were evaluated accordingly. The subject device passed all applicable testing.

Conclusion

Based on the intended use, technological characteristics, and performance testing results, the subject device is substantially equivalent to the predicate device.