



May 22, 2026

Genesee BioMedical, Inc.
James Cross
Quality Assurance Manager
700 W. Mississippi Ave Unit D-5
Denver, Colorado 80223

Re: K252917

Trade/Device Name: ATLAAS (Atraumatic Left Atrial Appendage System)
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: Class II
Product Code: PZX
Dated: September 11, 2025
Received: September 12, 2025

Dear James Cross:

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

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N. Trivedi -S
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Katherine Trivedi
Assistant Director
DHT2B: Division of Circulatory Support,
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Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K252917

Device Name
ATLAAS (Atraumatic Left Atrial Appendage System) (AD)

Indications for Use (Describe)

ATLAAS is indicated for the exclusion of the heart's Left Atrial Appendage, performed under direct visualization, 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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Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

Applicant Name	Genesee BioMedical, Inc.
Applicant Address	700 W. Mississippi Ave Unit D-5 Denver CO 80223 United States
Applicant Contact Telephone	303-777-3000
Applicant Contact	Mr. James Cross
Applicant Contact Email	jcross@geneseebiomedical.com

Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	ATLAAS (Atraumatic Left Atrial Appendage System) (AD)
Common Name	Implantable clip
Classification Name	Left Atrial Appendage Clip, Implantable
Regulation Number	878.4300
Product Code(s)	PZX

Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K233407	AtriClip Flex V LAA Exclusion	PZX
K232295	Penditure LAA Exclusion	PZX

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

The ATLAAS (Atraumatic LAA System) is a single-use implantable device designated to externally exclude the left atrial appendage (LAA) of the heart. The device is provided sterile for one-time use only. ATLAAS is composed of two noncompliant PET balloons designed to be inflated and serve as a linear epicardial clamp to exclude the LAA at its base while providing a cushion against the atrial wall. The balloons are supported by a PEEK plastic housing clip that latches and secures the device to the LAA. The device is covered with polyester braid which provides friction to prevent device migration, allows ingrowth of tissue, and allows attachment of a reusable GBI holder and applicator. The device can be attached to and detached from the holder. The PEEK housing of ATLAAS has a latching mechanism that can be unlocked by the holder to allow the device to be removed and repositioned multiple times. The clip is deployed and is left as a permanent implant. ATLAAS is available in the following lengths to accommodate different sizes of LAA: 35 mm, 40 mm, 45 mm, and 50 mm.

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

ATLAAS is indicated for the exclusion of the heart's Left Atrial Appendage, performed under direct visualization, 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.

Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

ATLAAS has identical indications for use as the predicate device AtriClip Flex V LAA Exclusion.

GBI evaluated ATLAAS and compared to AtriClip Flex V LAA Exclusion System as a predicate device with Penditure LAA as a reference device in accordance with Appendix A – 510(k) Decision Making Flowchart along with the guidance The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications. The subject device and predicate device have identical principles of operation and sizing. ATLAAS is composed of two noncompliant PET balloons attached to a PEEK clip, all enclosed in a polyester braid. The balloons are designed to be inflated and serve as a linear epicardial clamp to exclude the LAA at its base while providing a cushion against the atrial wall. The PEEK housing clip attaches and secures the device to the LAA, and includes a latching mechanism to allow the device to be repositioned. These technological differences between ATLAAS and the predicate device are to ensure a complete closure at the true base of the LAA. ATLAAS is made from commonly used biocompatible materials and testing has demonstrated that the device performs substantially equivalent to the predicate device and will remain in place to completely necrotize the LAA. A usability and human factors engineering study of ATLAAS of novel users, including an acute animal evaluation, found the implantation of ATLAAS and AtriClip Flex V to be comparable. The technological differences do not raise different questions of safety and effectiveness.

Non-Clinical and/or Clinical Tests Summary & Conclusions

Nonclinical Bench testing was completed as follows:

- Stress Analysis
- Closure System Verification
- Pressure Occlusion Verification
- Device Migration Testing
- Performance Testing
- Aged Performance Testing
- Usability and Human Factors Testing
- Sterilization validation per ISO 11137-1

Biocompatibility testing was completed as follows:

- Cytotoxicity per ISO 10993-5
- Material-Mediated Pyrogenicity per USP <151>
- Sensitization per ISO 10993-10
- Intracutaneous Irritation per ISO 10993-23

Chemical characterization testing per ISO 10993-18 and toxicological risk assessment per ISO 10993-17 was completed to address the following:

- Toxicity (acute, sub-acute/sub-chronic, & chronic)
- Genotoxicity
- Carcinogenicity

A 90-day GLP canine animal study was completed to demonstrate device effectiveness and safety.

The Usability and Human Factors Testing found the device to be substantially equivalent to the predicate device among intended users and included an acute animal study comparing ATLAAS to the predicate for equivalence.

Genesee BioMedical, Inc. considers the ATLAAS to be substantially equivalent to the predicate device. This conclusion is based upon the fact that devices have an identical intended use, and there are no clinical or biological differences, in performance testing that raise new questions of safety and effectiveness. Any technical differences between ATLAAS and the predicate device were evaluated and tested to determine substantial equivalence. The 90-day GLP animal study demonstrates that ATLAAS excludes the left atrial appendage with no adverse effects. Nonclinical testing demonstrates that the balloons remain inflated and provide equal pressure across the entire width of the appendage for up to 11 months. The design and materials of ATLAAS are able to withstand the pressures and forces exerted by the left atrium and prevent device migration after implantation. The usability testing of novel users demonstrates that the device works as expected with the accessories including closing, opening, and repositioning of the device. The usability study also included an acute animal evaluation comparing ATLAAS to the predicate for equivalence. Based on the testing, ATLAAS has demonstrated that it is substantially equivalent and performs as well as the predicate device.