October 29, 2025

Abbott Medical
Bryan Soto
Senior Regulatory Affairs Specialist
177 County Road B East
St. Paul, Minnesota 55117

Re: K253232
Trade/Device Name: Seguin Annuloplasty Ring
Regulation Number: 21 CFR 870.3800
Regulation Name: Annuloplasty Ring
Regulatory Class: Class II
Product Code: KRH
Dated: September 26, 2025
Received: September 29, 2025

Dear Bryan Soto:

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,

JULIE B. MACKEL -S

Samuel Raben
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)*
K253232

Device Name
Seguin Annuloplasty Ring

Indications for Use *(Describe)*
The Seguin Annuloplasty Ring is indicated for use in the repair of mitral valves that are diseased or damaged due to acquired or congenital processes.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) #: K253232

510(k) Summary

Prepared on: 2025-10-28

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Abbott Medical
Applicant Address	177 County Road B East St. Paul MN 55117 United States
Applicant Contact Telephone	1(651)269-1805
Applicant Contact	Mr. Bryan Soto
Applicant Contact Email	bryan.soto1@abbott.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Seguin Annuloplasty Ring
Common Name	Seguin Annuloplasty Ring
Classification Name	Ring, Annuloplasty
Regulation Number	870.8300
Product Code(s)	KRH

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K092310	SJM Seguin Annuloplasty Ring	KRH

Device Description Summary

21 CFR 807.92(a)(4)

The Seguin Annuloplasty Ring (SARP) is a semi-rigid or semi-flexible annuloplasty ring designed to support mitral valve repair. The ring is constructed from a polyethylene core covered by a knitted polyester sewing cuff. The Seguin Ring is sterilized by EO sterilization and supplied sterile. The Seguin ring is offered in sizes 24-40mm in increments of 2 mm.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Séguin™ Annuloplasty Ring is indicated for use in the repair of mitral valves that are diseased or damaged due to acquired or congenital processes.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use of the device currently in scope of this submission are identical to those of the predicate device.

Technological Comparison

21 CFR 807.92(a)(6)

There is no difference in the technological characteristics between the device in scope of this submission to the predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

There was no clinical testing needed for this determination. The following non-clinical testing was conducted in support of a substantial

equivalence determination:
- Design Validation: Design validation testing was successfully conducted and the test results support a 5 year shelf life.
- Packaging: A real time aging testing was conducted and packaging system successfully met all the applicable stability requirements at 5-year timepoint.