October 28, 2022

Syntheon
% Elena Jugo
Regulatory Consultant
Caraballo Consulting, LLC
11037 Bitternut Hickory Lane
Boynton Beach, Florida 33437

Re: K220305
Trade/Device Name: Syntheon LAA Exclusion System
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: Class II
Product Code: PZX
Dated: September 27, 2022
Received: September 28, 2022

Dear Elena Jugo:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

for Rachel Neubrander
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)*
K220305

Device Name
Syntheon LAA Exclusion System

Indications for Use *(Describe)*
The Syntheon 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 any other appropriate viewing technology.

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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5 - 510(k) Summary

Date Summary Prepared: January 31, 2022

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Trade Name: LAA Exclusion System

Regulation Number: 21 CFR 878.4300

Device Common or Classification Name: Left Atrial Appendage Clip, Implantable

Product Class: Class II

Product Panel: Cardiovascular

Product Code: PZX

Predicate Device: K210293, AtriCure AtriClip LAA Exclusion System

5.1 Device Description

The Syntheon LAA Exclusion System consists of a single use, sterile, self-closing, implantable Clip preloaded on a single use delivery system. When closed, the implant applies pressure to ensure exclusion of the left atrial appendage (LAA). Once the clip is deployed, it remains as a permanent implant. The implantable clip is available in lengths of 35mm. 40mm, 45mm, and 50mm to accommodate different sizes of LAA. The Syntheon LAA Selection Guide is a sterile, single use, disposable surgical accessory device to assist the physician in selecting the appropriately sized clip implant for each individual patient.

5.2 Indications for Use

The Syntheon 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 any other appropriate viewing technology.

5.3 Technological Characteristics and Basis for Substantial Equivalence

The Syntheon LAA Exclusion System, subject of this 510(k) submission, is substantially equivalent in its intended use/indications for use, technology/principal of operation, biocompatibility of materials, sterilization method and performance to the predicate device, the AtriCure AtriClip LAA Exclusion System.

A comparison of the technological characteristics of the subject device and the predicate device is summarized in **Table 5.3.1**.

Table 5.3.1 - Comparison Between the Syntheon LAA Exclusion System and Predicate Device

Parameter	Subject Device Syntheon LAA Exclusion System	Predicate Device AtriCure AtriClip LAA Exclusion System 510(k) # K210293	Equivalence Comparison
Indications for Use	The Syntheon 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**
Product Code	PZX	PZX	**Same**
Regulation No.	21CFR878.4300	21CFR878.4300	**Same**
Classification	Class II	Class II	**Same**
Components	Implantable clip and disposable clip applier (delivery system)	Implantable clip and disposable clip applier	**Same**
Principle of Operation	The clip is comprised of two springs biasing two bars together with constant force for the exclusion of the left atrial appendage.	The clip is comprised of two springs biasing two bars together with constant force for the exclusion of the left atrial appendage.	**Same**
Clip Size	Clip Size LAA Size Range: • 35 mm: 29-35 mm • 40 mm: 34-40 mm • 45 mm: 39-45 mm • 50 mm: 44-50 mm	Clip Size LAA Size Range: • 35 mm: 29-35 mm • 40 mm: 34-40 mm • 45 mm: 39-45 mm • 50 mm: 44-50 mm	**Same**
Clip Opening	Tip opens to a minimum of 12 mm at the distal end.	Gillinov-Cosgrove Clip: Opens 12.5 mm $\pm$ 1.5 mm as measured between the beams of the clip. PROV Clip: Opens to a minimum of 12 mm at the distal end and 4 mm at the proximal end of the clip.	Same as PROV, design verification testing for the Syntheon LAA Exclusion system has demonstrated a proximal opening >4 mm for all implant sizes. The implant functions as intended.
Biocompatibility	Materials have been assessed based on ISO 10993 and are	Materials have been assessed based on ISO 10993 and are	**Same**

Table 5.3.1 - Comparison Between the Syntheon LAA Exclusion System and Predicate Device

Parameter	Subject Device Syntheon LAA Exclusion System	Predicate Device AtriCure AtriClip LAA Exclusion System 510(k) # K210293	Equivalence Comparison
	commonly employed in tissue contacting devices.	commonly employed in tissue contacting devices.	
Single Use Only	Yes	Yes	**Same**
Sterilization	Gamma Radiation	Gamma Radiation	**Same**
Pyrogenicity	Nonpyrogenic	Nonpyrogenic	**Same**
MRI Compatibility	MR Conditional	MR Conditional	**Same**

5.4 Performance Data

Design verification and validation were performed to ensure that the Syntheon LAA Exclusion System 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
- Packaging Testing
- Shelf-life Testing
- Bench-top Validation Testing
- Animal Validation Testing

All pre-determined acceptance criteria were met. The data demonstrate that the Syntheon LAA Exclusion System is substantially equivalent to the predicate device.

5.5 Biocompatibility Testing

The Syntheon LAA Exclusion System was assessed for biocompatibility in accordance with ISO 10993-1:2018, "Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process". The clip component of the LAA Exclusion System is an implantable device that is in long-term contact with the body (> 30 days), while the clip delivery system has limited contact (≤ 24 hours). **Table 5.5.1** lists the tests performed to ensure that each component is biocompatible. The Syntheon LAA Exclusion System biocompatibility testing met all requirements.

Table 5.5.1 - Biocompatibility Tests Performed on the LAA Exclusion System

Test	Implant, Long-Term Contact (> 30 days)	Delivery System - External Communicating, Limited Contact (≤ 24 hours)
Chemical Characterization	✓	✓
Cytotoxicity	✓	✓
Sensitization	✓	✓
Irritation	✓	✓
Acute Systemic Toxicity	✓	✓
Pyrogenicity	✓	✓
Sub-Acute/Sub-Chronic Toxicity	✓	N/A
Genotoxicity • Ames Mutagenicity • In Vitro Mouse Lymphoma Mutagenesis	✓	
Implantation • 1-, 4-, and 13-weeks	✓	

5.6 Conclusion

Review of the verification and validation test data as well as comparison of the device classification, indications for use, operating principle, technological characteristics, sterility, and biocompatibility, demonstrate that the subject device, the Syntheon LAA Exclusion System, is substantially equivalent to the predicate AtriCure AtriClip LAA Exclusion System, K210293, cleared on March 3rd, 2021. Any differences between the subject and the predicate devices do not raise any issues of safety and effectiveness.