August 30, 2023

Syntheon, LLC
Toygar Unal
Director of Quality
13755 SW 119 Avenue
Miami, Florida 33186

Re: K232295
Trade/Device Name: LAA Exclusion System
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: Class II
Product Code: PZX
Dated: July 26, 2023
Received: August 1, 2023

Dear Toygar Unal:

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,

Katherine N. Trivedi -S

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)*
K232295

Device Name
LAA Exclusion System

Indications for Use *(Describe)*
The 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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510(k) Summary

Date Summary Prepared: July 26, 2023

Applicant:

Syntheon
13755 SW 119 Avenue
Miami, FL 33186

Contact Person:

Toygar Unal
Director of Quality
Syntheon
13755 SW 119 Avenue
Miami, FL 33186
Telephone: 1-973-997-8532
Email: tunal@syntheon.com

Trade Name:

LAA Exclusion System

Device Common or Classification Name:

Left Atrial Appendage Clip, Implantable

Review Panel:

Cardiovascular

Product Class:

Class II

Product Code:

PZX

Predicate Device:

K220305, Syntheon LAA Exclusion System

Device Description:

The 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 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.

Indications for Use:

The 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.

Comparison of Technological Characteristics with the Predicate Device (LAA Exclusion System, K220305):

The modifications to the LAA Exclusion System include minor changes to the following, dimensional and shape changes to the release wire, an increase in the recapture force specification, addition of a new specification around recapture without depressing the release trigger, and an update to the IFU instructions for use to instruct the user to depress the release trigger during recapture. A comparison of the technological characteristics of the subject device and the predicate device is summarized in Table 1.

Table 1: Comparison of Technological Characteristics			
Characteristic	**Subject Device LAA Exclusion System**	**Predicate Device LAA Exclusion System (K220305)**	**Rationale for Substantial Equivalence**
Indications for Use	The 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 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.	Identical
Product Code	PZX	PZX	Identical
Regulation No.	21CFR878.4300	21CFR878.4300	Identical
Classification	Class II	Class II	Identical
Components	Implantable clip and disposable clip applier (delivery system)	Implantable clip and disposable clip applier (delivery system)	Identical
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.	Identical
Clip Size	Clip Size LAA Size Range:	Clip Size LAA Size Range:	Identical

Table 1: Comparison of Technological Characteristics			
Characteristic	**Subject Device LAA Exclusion System**	**Predicate Device LAA Exclusion System (K220305)**	**Rationale for Substantial Equivalence**
	• 35 mm: 39-35 mm • 40 mm: 34-40 mm • 45 mm: 39-45 mm • 50 mm: 44-50 mm	• 35 mm: 39-35 mm • 40 mm: 34-40 mm • 45 mm: 39-45 mm • 50 mm: 44-50 mm	
Clip Opening	Tip opens to a minimum of 12 mm at the distal end.	Tip opens to a minimum of 12 mm at the distal end.	Identical
Biocompatibility	Materials have been assessed based on ISO 10993 and are commonly employed in tissue contacting devices.	Materials have been assessed based on ISO 10993 and are commonly employed in tissue contacting devices.	Identical
Single Use Only	Yes	Yes	Identical
Sterilization	Gamma Radiation	Gamma Radiation	Identical
Pyrogenicity	Nonpyrogenic	Nonpyrogenic	Identical
MRI Compatibility	MR Conditional	MR Conditional	Identical

Performance Data:

Design verification testing was performed to ensure that the modified LAA Exclusion System continues to meet its performance specifications. The following tests were conducted to demonstrate equivalence to the predicate device.

- Bent Shaft Functional Check
- Trigger Actuation Force
- Deployment/Recapture
- Clip Orientation
- One Pin Mis-Capture
- Recapture Indicator
- Implant Tip Opening
- Implant Root Opening
- Implant Deployment Force
- Implant Recapture Force
- Implant Retention Strength
- Implant Forced Pull-Off
- Max Dose Sterilization

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

Conclusion:

Review of the design verification test data as well as comparison of the indications for use, operating principle, technological characteristics, sterility, and biocompatibility demonstrate that the modified LAA Exclusion System is substantially equivalent to the predicate LAA Exclusion System cleared under K220305.