September 18, 2023

Boston Scientific Inc.
James Shene
Senior Regulatory Affairs Specialist
1120 South Capital of Texas Hwy
Suite 300
Austin, Texas 78746

Re: K232544
Trade/Device Name: Apollo ESG NXT System,
Apollo REVISE NXT System
Regulation Number: 21 CFR 876.5983
Regulation Name: Endoscopic suturing device for altering gastric anatomy for weight loss
Regulatory Class: Class II
Product Code: QTD
Dated: August 18, 2023
Received: August 22, 2023

Dear James Shene:

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,

Glenn B. Bell -S

Glenn B. Bell
Director
DHT3A: Division of Renal,
Gastrointestinal, Obesity
and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology 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)*
K232544

Device Name
Apollo ESG NXT System

Indications for Use *(Describe)*
The Apollo ESG NXT System is intended to be used by trained gastroenterologists or surgeons that perform bariatric procedures to facilitate weight loss by reducing stomach volume through endoscopic sleeve gastroplasty in adult patients with obesity with BMI between 30-50 kg/m2 who have not been able to lose weight, or maintain weight loss, through more conservative measures.

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.

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The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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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)*
K232544

Device Name
Apollo Revise NXT System

Indications for Use *(Describe)*
The Apollo REVISE NXT System is intended to be used by trained gastroenterologists or surgeons that perform bariatric procedures to facilitate weight loss in adult patients with obesity with BMI between 30-50 kg/m2 by enabling transoral outlet reduction as a revision to a previous bariatric procedure.

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

Owner's Name & Address:

Boston Scientific Coporation
300 Boston Scientific Way
Marlborough, MA 01752

Contact Person:

James Shene
Senior Regulatory Affairs Specialist
(512) 852-3793
james.shene@apolloendo.com

Date:

September 14, 2023

Trade Name:

Apollo ESG NXT™ System, Apollo REVISE NXT™ System

Common Name:

Endoscopic suturing device for altering gastric anatomy for weight loss

Product Code:

QTD

Classification:

Class II (21 CFR 876.5983)

Classification Name

Endoscopic suturing device for altering gastric anatomy for weight loss

Predicate Devices:

DEN210045 –Apollo ESG Sx System, Apollo Revise Sx System

Device Description

These devices are used to perform gastric remodelling through the placement of anchor-sutures and locking cinch device. The Apollo ESG NXT system is for intended for endoscopic sleeve gastroplasty (ESG) while the Apollo REVISE NXT device is intended for transoral outlet reduction, as a revision to a previous bariatric procedure. The two device systems differ in terms of the number of anchor-sutures and cinches needed to perform ESG and TORe procedures.

Both systems are comprised of a Needle Driver Assembly and Anchor Exchange Device, and accessories such as the Tissue Helix, Suture Cinch and Suture-Anchor Assembly devices. All devices are sterile packaged and designed for single use and are manufactured from various thermoplastic, silicone, stainless steel and other medical grade materials.

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Apollo ESG NXT and Apollo REVISE NXT

The Apollo ESG NXT and Apollo REVISE NXT needle driver assembies are designed to be compatible with single channel endoscopes. The endcap assembly of the needle driver is mounted onto the endoscope using polyester medical tape. The external catheter sheath has two working channels through which the Anchor Exchange and other accessories can operate, independent of the endoscope channel. The needle driver assembly also incorporates a pull string feature that, when pulled, allows the physician to further control the retroflexion capabilities of the endoscope.

The handle of the Needle Driver Assembly is squeezed to actuate the needle body and exchange the proprietary Suture-Anchor Assembly with the Anchor Exchange to perform stitching operations. A previously cleared Tissue Helix is provided with Apollo ESG NXT while the NXT Tissue Helix Pro is provided with Apollo REVISE NXT. Both instruments are used for manipulating tissue into the suturing window of the needle driver assembly. These devices also include a matching number of anchor-sutures and cinches to perform the gastroplasty or revision procedure.

NXT Tissue Helix Pro

The NXT Tissue Helix Pro is used to acquire tissue by rotating the device's handle to to gather tissue onto the exposed exposed helix coil. The acquired tissue is then pulled into proximity of the needle body to complete the stitching operation. Tissue is released by rotating the handle in the opposite direction.

Indications for Use:

The APOLLO ESG System is intended to be used by trained gastroenterologists or surgeons that perform bariatric procedures to facilitate weight loss by reducing stomach volume through endoscopic sleeve gastroplasty in adult patients with obesity with BMI 30 -50 kg/m^2 who have not been able to lose weight, or maintain weight loss, through more conservative measures.

The APOLLO REVISE System is intended to be used by trained gastroenterologists or surgeons that perform bariatric procedures to facilitate weight loss in adult patients with obesity with BMI 30 - 50 kg/m^2 by enabling transoral outlet reduction as a revision to a previous bariatric procedure.

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Technological Characteristics:

Modifications to design and materials as compared to the predicate device cleared via DEN210045 are as follows:

Apollo ESG NXT and Apollo Revise NXT

- "MaxFlex" Feature: A new feature, integrated into the needle driver assembly, that incorporates the use of a "pull string" to provide physicians with the ability to further control the retroflexion capabilities of their endoscope. This feature does not need to be used by the physician.
- Endoscope Attachment Method : The method and materials used to attach the needle driver to the endoscope were updated.
- Design/Material Modifications: New materials and design modifications were implemented in order to improve product durability and the manufacturability of the device.

NXT Tissue Helix Pro

The design of this tissue helix has been updated to lower catheter stiffness and improve maneuverability. Additionally, the handle interface was updated to allow the device to be controlled entirely by the physician and the helix tip was updated to an electro-cut design.

Non-Clinical Performance Data:

Appropriate product testing was performed on the subject device to evaluate conformance to product specifications and equivalence to the predicate devices. Verification and validation for the proposed system of devices was conducted in accordance with written protocols, previously applied to the predicate device. All devices were evaluated to their individual functional and reliability requirements, as well as system compatibility.

Performance Testing

Bench testing included suture drag testing, tensile testing, torque load testing, endoscope compatibility, sterility, reliability and bond strength. Additionally, the Tissue Helix Pro device was tested for tissue acquisition reliability.

Functional Testing

An ex vivo model was utilized, using the same test methods as the predicate to evaluate the device function and intended use.

Packaging Integrity

Packaging Integrity was confirmed by repeating testing in accordance with ASTM F2096-11, ASTM F1980-21, ASTM D4169-22 and ASTM F88/F88M-21.

Acceptance criteria were met in each of the studies listed above. The results confirmed equivalency between the subject and predicate devices, and that no new issues of safety or efficacy were raised.

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Biocompatibility: Biocompatibility testing and toxicological assessments were performed on subject OverStitch devices in accordance with their risk category requirements, as defined in ISO 10933-1. Testing included cytotoxicity, irritation and skin sensitization, systemic toxicity, and material mediated pyrogenicity.

Clinical Performance Data: The DEN210045 clearance associated with the predicate devices created a special controls. One control was for clinical performance, specifically that the device performs as intended under anticipated conditions of use evaluating weight loss and adverse events. Another control was to ensure physicians were trained on the use of the systems to remodel gastric anatomy. These devices, which use the De Novo clearance devices as predicates, leverage the clinical data presented in that De Novo. The ESG and outlet revisions procedures performed with these devices are the same (same implant placements and the same implants), and training requirements are the same. There is reasonable assurance that the weight loss and adverse events will the equivalent to the predicate.

Basis of Substantial Equivalence: Based on a comparison of indications for use and technological characteristics, the proposed devices have demonstrated substantial equivalence to their predicates.

Table 1: Summary Table of Equivalence

	Predicate Apollo ESG Sx and Apollo Revise Sx (DEN210045)	**Apollo ESG NXT and Apollo Revise NXT**
Indications for Use	The APOLLO ESG System is intended to be used by trained gastroenterologists or surgeons that perform bariatric procedures to facilitate weight loss by reducing stomach volume through endoscopic sleeve gastroplasty in adult patients with obesity with BMI 30 -50 kg/m2 who have not been able to lose weight, or maintain weight loss, through more conservative measures. The APOLLO REVISE System is intended to be used by trained gastroenterologists or surgeons that perform bariatric procedures to facilitate weight loss in adult patients with obesity with BMI 30 - 50 kg/m2 by enabling transoral outlet reduction as a revision to a previous bariatric procedure.	Same, with the revision of the product name (APOLLO ESG NXT and APOLLO REVISE NXT).
Endoscope Compatibility	Compatible with single channel endoscopes having an outer diameter range of 8.8 to 9.8 mm	Same
Working Length	Maximum working length of 110 cm	Same
Sterilization Method	EO	Same
Shelf Life	3 years	1 year
Usage	Single-use	Same

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	Predicate Apollo ESG Sx and Apollo Revise Sx (DEN210045)	**Apollo ESG NXT and Apollo Revise NXT**
Functional Durability	Validated to perform 8 stiches for each of 8 sutures.	Same
Biocompatibility	Tested per ISO 19993.	Same
MR Compatibility	Safe with 1.5 and 3 T MR scanners with spatial field gradient of 2500 Gauss/cm (extrapolated or less) and SAR of 2.0 W/kg for 15 minutes of continuous scanning	Same
Labeling (Special Control from DEN210045)	Labeling must include a summary of clinical performance testing with the device, including a discussion of adverse event sand clinical benefit reported as percent total body weight loss; and shelf-life.	Same
Training (Special Control from DEN210045)	Training must be provided so that upon completion of the training program, the user can use the device correctly to approximate tissue to alter the gastric anatomy for thep purpose of weight loss with minimal implact to the safety of the patient.	Same