



July 12, 2022

Apollo Endosurgery, Inc.
% Jonathan Kahan
Partner
Hogan Lovells US LLP
555 13th Street NW
Washington, DC 20009

Re: DEN210045
Trade/Device Name: APOLLO ESG System, APOLLO ESG SX System,
APOLLO REVISE System, APOLLO REVISE SX 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: September 30, 2021
Received: September 30, 2021

Dear Jonathan Kahan:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the APOLLO ESG System, APOLLO ESG SX System, APOLLO REVISE System, APOLLO REVISE SX System, a prescription device under 21 CFR Part 801.109 with the following indications for use:

The APOLLO ESG and ESG SX Systems are intended to be used by trained gastroenterologists or surgeons that perform bariatric procedures to facilitate weight loss by reducing stomach volume through endoscopic sleeve gastropasty 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 and REVISE SX Systems are 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.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the APOLLO ESG System, APOLLO ESG SX System, APOLLO REVISE System, APOLLO REVISE SX System, and substantially equivalent devices of this generic type, into Class II under the generic name endoscopic suturing device for altering gastric anatomy for weight loss.

FDA identifies this generic type of device as:

Endoscopic suturing device for altering gastric anatomy for weight loss. An endoscopic suturing device for altering gastric anatomy for weight loss uses suturing to approximate gastric tissue to restrict the volume of the stomach for the intended purpose of weight loss.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On September 30, 2021, FDA received your De Novo requesting classification of the APOLLO ESG System, APOLLO ESG SX System, APOLLO REVISE System, APOLLO REVISE SX System. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the APOLLO ESG System, APOLLO ESG SX System, APOLLO REVISE System, APOLLO REVISE SX System into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request FDA has determined that, for the previously stated indications for use, the APOLLO ESG System, APOLLO ESG SX System, APOLLO REVISE System, APOLLO REVISE SX System can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Identified Risks to Health	Mitigation Measures
Device- and/or procedure-related adverse events, including: <ul style="list-style-type: none"> • Death • Gastrointestinal bleeding • Obstruction • Perforation • Injury to organs adjacent to the stomach • Perigastric leak • Nausea 	Clinical performance testing Non-clinical performance testing Labeling Training Sterilization validation Shelf life testing

<ul style="list-style-type: none"> • Infection • Pain • Pneumoperitoneum • Pneumothorax • Pulmonary embolism 	
Weight gain	Clinical performance testing Labeling
Adverse tissue reaction	Biocompatibility evaluation

In combination with the general controls of the FD&C Act, the endoscopic suturing device for altering gastric anatomy for weight loss is subject to the following special controls:

- (1) Clinical performance testing must demonstrate the device performs as intended under anticipated conditions of use and evaluate the following:
 - (i) Weight change; and
 - (ii) All adverse events.
- (2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:
 - (i) Performance bench testing in a simulated use model must verify functional aspects of the device design and support device durability during clinical use;
 - (ii) Dimensional specifications must be verified; and
 - (iii) Tensile strength testing must be performed for all articulating components.
- (3) Performance data must support the shelf life of the device by demonstrating continued package integrity and device functionality over the labeled shelf life.
- (4) Performance data must demonstrate the sterility of the patient-contacting components of the device.
- (5) The patient-contacting components of the device must be demonstrated to be biocompatible.
- (6) 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 the purpose of weight loss with minimal impact to the safety of the patient.
- (7) Labeling must include:
 - (i) A summary of clinical performance testing with the device, including a discussion of adverse events and clinical benefit reported as percent total body weight loss; and
 - (ii) A shelf life.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the endoscopic suturing device for altering gastric anatomy for weight loss they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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 FD&C Act; 21 CFR 1000-1050).

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact April Marrone, Ph.D., MBA at 240-402-6510.

Sincerely,

Courtney H. Lias, Ph.D.
Director
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health