July 26, 2024

Hemostasis LLC
Lakshmi Ganesh Bollina
Regulatory Affairs Specialist
5000 Township Parkway
St. Paul, Minnesota 55110

Re: K234131
Trade/Device Name: Resolv Endoscopic Hemostat System
Regulation Number: 21 CFR 878.4456
Regulation Name: Hemostatic Device For Intraluminal Gastrointestinal Use
Regulatory Class: Class II
Product Code: QAU
Dated: June 25, 2024
Received: June 26, 2024

Dear Lakshmi Ganesh Bollina:

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.

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,

Tek N. Lamichhane -S

Digitally signed by Tek N. Lamichhane -S
Date: 2024.07.26 14:56:04 -04'00'

Tek N. Lamichhane, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
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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)*
K234131

Device Name
Resolv Endoscopic Hemostat System

Indications for Use *(Describe)*
The Hemostasis Resolv Endoscopic Hemostat System is intended for use under the care of a health care professional for hemostasis of upper nonvariceal gastrointestinal bleeding, excluding Forrest Ia classification of bleeding.

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
K234131
Resolv™ Endoscopic Hemostat System

Date Prepared: 25 July 2024

Submitter: Hemostasis, LLC
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Contact: Mr. Lakshmi Ganesh Bollina
Regulatory Affairs Specialist
5000 Township Parkway
St. Paul, MN 55110
Telephone: 651- 855-1466

Proprietary Name: Resolv™ Endoscopic Hemostat System

Common/Usual Name: Endoscopic Hemostat

Classification: Hemostatic device for intraluminal gastrointestinal use,
Product Code QAU, Class II, 21 CFR 878.4456

Predicate Device: EndoClot Polysaccharide Hemostatic System K190677

Reference Device: NexStat® Plus Topical Hemostat K122886

Establishment Registration Number: 3007225047

Description:
The Resolv™ Endoscopic Hemostat System is a sterile prescription device intended for use under the care of a health care professional for hemostasis of nonvariceal upper gastrointestinal bleeding, excluding Forrest Ia classification of bleeding. The device consists of a hemostat powder and dispenser components provided in a tray with a Tyvek lid acting as the sterile barrier. The hemostat powder is further contained within in a capped cartridge and packaged in a foil pouch. The dispenser components include a flow dispenser, two catheter tubing sets and a gas source tubing set. The gas source tubing set is connected to a medical CO_2 gas source that is flow and pressure controlled. The endoscope distal end controls are used to aim the flow and placement of the hemostat powder. The trigger is released to stop the flow of powder. The device contains a maximum of 16.7 grams of hemostat powder and no more than 2 devices (33.4 grams) may be used on a patient either in a single procedure or in conjunction with rebleeding up to 10 days after the initial procedure. If 2 devices (33.4 grams) have been used in the initial procedure an alternate modality must be used should rebleeding occur.

The hemostat powder is identical to the commercially available topical hemostat, NexStat® Plus which received 510(k) clearance with K122886 as a topical wound dressing, comprised of plant-based polysaccharides.

Indications for Use:
The Hemostasis Resolv™ Endoscopic Hemostat System is intended for use under the care of a health care professional for hemostasis of non-variceal upper gastrointestinal bleeding, excluding Forrest Ia classification of bleeding.

Substantial Equivalence:
The Resolv™ Endoscopic Hemostat System is substantially equivalent to the primary predicate EndoClot® Polysaccharide Hemostatic System, 510(k) Number K190677 (QAU), clearance date 01/29/2021, for the following reasons:

- Both have the same FDA Classification, Intended use and target population.
- Both are sterile, single use devices that deliver a plant-based polysaccharide powder to the GI bleeding site.
- Both contain materials proven biocompatible for their intended use in accordance with ISO 10993-1.

The primary differences appear to be the gas source, flow rate and digestibility in the GI Tract.

- Gas Source: Resolv™ utilizes the hospital supply CO_2, while the EndoClot® PHS utilizes air drawn from OR and filtered.
- Gas Flowrate: The flow is set within the range of 0.6 to 1.0 slpm for Resolv™, while for Endoclot the flow is based on gas pressure defined in Endoclot IFU.
- Digestibility in the GI Tract leading to release of sugar molecules: The Resolv hemostat powder is 13% digestible where Endoclot PHS powder is fully digested.

In addition, the powder hemostat used in the Resolv™ is identical to the Class II topical hemostat, NexStat® Plus, in terms of material composition, mechanism of action, manufacturing and sterilization. Due to the differences in Intended Use and delivery system, Resolv™ Endoscopic Hemostat System has undergone additional biocompatibility testing, sterilization validation, packaging testing and in vivo and non-clinical performance testing in accordance with its intended use special controls specified in 21 CFR 878.4456 for a Hemostatic device for intraluminal gastrointestinal use.

Summary of Non-Clinical Performance Data

Biocompatibility:
Biocompatibility testing was performed using ISO 10993 – Biological Evaluation of Medical Devices and FDA guidance document Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process" dated Sept.8, 2023. The Hemostasis Resolv™ Endoscopic Hemostat System complies with the biocompatibility requirements for its intended use.

Sterilization, Packaging, Shelf Life:
The Hemostasis Resolv™ Endoscopic Hemostat System is sterilized using a validated gamma radiation method to assure a sterility assurance level (SAL) of 10^{-6}. The packaged device has been successfully tested for package integrity and device functionality over the labeled shelf life of 24 months.

Performance Bench Testing:
Design verification testing was performed for the Resolv™ Endoscopic Hemostat System to demonstrate physical and functional requirements were met.

Animal Performance Testing:
In vivo animal studies have been conducted to support the substantial equivalence claims of Resolv™ Endoscopic Hemostat system as compared to the predicate device Endoclot®. The objective of the study was to validate the efficacy and safety of Resolv™ Endoscopic Hemostat system in a porcine animal model for bleeding control in the upper GI tract. The results of the animal study demonstrated that the Resolv™ did meet the in vivo safety and performance requirements of the special controls in 21 CFR 878.4456 by effectively delivering the hemostat to the bleeding site and achieving hemostasis and meeting all the safety endpoints and is substantially equivalent to the predicate.

Clinical Performance Testing:
A human clinical evaluation was conducted in India to support the safety and effectiveness of the use of Resolv™ Endoscopic Hemostat System. Resolv™ was studied in 59 subjects undergoing endoscopic upper GI procedures. Hemostasis was achieved in 100% of patients with an endoscopically confirmed re-bleed rate of 3.4% and an all-cause rebleed rate of 5.1%.

Hemostat System	Forrest Bleeding Classification	Number of Subjects	Hemostasis %	Rebleed Rate %	
				Endoscopically Confirmed	All Cause
Resolv	Ib	59	100%	3.4%	5.1%

Real world evidence provided for the Resolv Endoscopic Hemostat System support that the Resolv is substantially equivalent to the predicate in all aspects of safety and efficacy.

Conclusion:
Utilizing FDA's Guidance for Industry and FDA Staff "Format for Traditional and Abbreviated 510(k)s" issued on September 13, 2019, a comparison of key characteristics demonstrates that the proposed device Resolv™ Endoscopic Hemostat System is substantially equivalent to the predicate device in terms of intended use and performance characteristics. The Resolv™ Endoscopic Hemostat System is as safe, as effective, and performs as well as the predicate device.

The substantial equivalence analysis supports that the Resolv™ Endoscopic Hemostat System presents no new concerns about safety and effectiveness and is suitable for its intended use.