December 13, 2024

Gastro Concepts, LLC
℅ Sarah Moss
Regulatory Consultant
Prime Path Medtech
1321 Upland Dr. #6792
Houston, Texas 77043

Re: K242668
Trade/Device Name: Gastro Concepts Air Assist
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FER, FED
Dated: November 13, 2024
Received: November 13, 2024

Dear Sarah Moss:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Sivakami Venkatachalam -S

for
Shanil P. Haugen, Ph.D.
Assistant 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242668

Device Name

Gastro Concepts Air Assist

Indications for Use *(Describe)*

Air Assist is intended to slide over the outer surface of an endoscope to facilitate endoscopic therapy by providing a manual, reversible method to control the insufflation (air/CO2) so the physician can better maintain an appropriate field of view.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

Submitter: Gastro Concepts

Company Contact Person: Rick Brown, President
Phone: (787) 642-2532
Email: rick.brown@gastroconcepts.com

Submission Correspondent: Sarah Moss, Regulatory Affairs Consultant
Address: 1321 Upland Dr. Suite 6792, Houston, TX 77043
Phone: (281) 795-1812
Email: smoss@primepathmedtech.com

Date Prepared: Sept 2024

Proprietary Name: Gastro Concepts Air Assist

Common Name: Anoscope and accessories

Product Code/CFR: FER, FED; 876.1500 Endoscope and accessories

Device Classification: Class II

Predicate Device: GelPOINT Path Transanal Access Platform (K110792)

Device Description:

The Gastro Concepts Air Assist Device is a single-use device that is used to aid in maintaining air/CO2 and insufflation during a colonoscopy. The Air Assist, a single-use device, comprises a cylindrical body with a conical-shaped tip and an open channel for endoscope insertion. Positioned against the anus (not inserted into the rectum), it forms a temporary seal, maintaining air/CO2 insufflation leading to adequate colonic distension for enhanced visualization.

Indications for Use:

Air Assist is intended to slide over the outer surface of an endoscope to facilitate endoscopic therapy by providing a manual, reversible method to control the insufflation (air/CO2) so the physician can better maintain an appropriate field of view.

Comparison to Predicate Devices

Specification	***Gastro Concepts Air Assist***	**GelPOINT Path Transanal Access Platform (*Predicate Device*)**	**Embrella™ Endoscopic Distal Attachment**	***Comparison Result***
510(k) Number		K110792	K190030	
Device Description	The Gastro Concepts Air Assist Device is a single-use device that is used to aid in maintaining air/CO2 and insufflation during a colonoscopy. The Air Assist, a single-use device, comprises a cylindrical body with a conical-shaped tip and an open channel for endoscope insertion. Positioned against the anus (not inserted into the rectum), it forms a temporary seal, maintaining air/CO2 insufflation leading to adequate colonic distension for enhanced visualization.	The GelPOINT Path is a sterile, single use, disposable surgical instrument designed to provide multiple instrument or camera access into the rectal cavity and lower sigmoid colon. The device is used in concert with standard laparoscopic instruments.	The proposed device Embrella™ Endoscopic Distal Attachment is an additional device, made of medical grade silicone rubber designed to attach to the distal end of the endoscope. Its shape is umbrella shaped, with six flexible wings that easily to fold backwards and forwards. It can be used to facilitate endoscopic therapy and maintain an appropriate endoscopic field of view. Embrella™ Endoscopic Distal Attachment has two models, one is EM-S-01, which is compatible with endoscopy distal diameter 12.8-14.5mm; the other is EM-S-02, which is compatible with endoscopy distal diameter 11.5-13.0mm.	Similar
Indication for Use	Air Assist is intended to slide over the outer surface of an endoscope to facilitate endoscopic therapy by providing a manual, reversible method to control the insufflation (air/CO2) so the physician can better maintain an appropriate field of view.	The GelPOINT Path is a sterile, single use, disposable surgical instrument designed to provide multiple instrument or camera access into the rectal cavity and lower sigmoid colon.	Embrella™ Endoscopic Distal Attachment is intended to be attached to the distal end of the endoscope to facilitate endoscopic therapy and maintain an appropriate endoscopic field of view.	Similar/In-Scope for Product Code
Product Code	FER	FER	FED	Same as predicate

Specification	***Gastro Concepts*** ***Air Assist***	**GelPOINT Path Transanal Access Platform (*Predicate Device)***	**Embrella™ Endoscopic Distal Attachment**	***Comparison Result***
Regulations	21CFR 876.1500	21CFR 876.1500	21CFR 876.1500	Equivalent
Class	2	2	2	Equivalent
Single Use	Yes	Yes	Yes	Equivalent
Scope Compatibility (diameter)	11.5-13mm	Not published	11.5-14.5mm	Similar
Device Functionality	Provides improved field of view by maintaining proper insufflation	Provides improved field of view by maintaining proper insufflation.	Provides improved field of view by prohibiting the surrounding tissues from block the distal end of the scope	Equivalent
Mechanism of Action	The device uses a physical barrier to impede pressure loss. This allows the colon to be insufflated, thus enlarging the operative space.	The device uses a physical barrier to impede pressure loss. This allows the colon to be insufflated, thus enlarging the operative space.	Flexible wings that easily fold backwards and forwards. It can be used to facilitate endoscopic therapy and maintain an appropriate endoscopic field of view.	Equivalent
Device Placement	Device is placed immediately adjacent to the anus	Device is inserted into the anus	Device is attached to the distal end of the scope and inserted into the body cavity.	Not equivalent (Air assist is less invasive)
Supplied Sterile/Non-Sterile	Non-sterile	Sterile	Sterile	Not equivalent (Air assist is not inserted into the body)
Materials	Silicone Rubber	Gel material	Silicone Rubber	Similar to predicate Equivalent to reference
Biocompatibility: ISO 10993-1	Yes	Yes	Yes	Equivalent
Shelf Life	6 months	One Year	One Year	Similar

Performance Testing (Bench)

The following bench tests were performed on the Gastro Concepts Air Assist Device:

- Dimensional Testing
- Simulated Use
- Mechanical Properties: Structural integrity, compression and tension strength
- Leak Rate and Sealing Capability

Testing was conducted to establish that the Gastro Concepts Air Assist device can withstand clinically relevant mechanical forces. Leak testing was also completed to demonstrate a reduction in air loss during insufflation. The bench testing proved that the Air Assist device was able to withstand forces greater than expected during clinical use and that the device was successful in reducing the leak rate during simulated colonic insufflation.

The Air Assist device meets the requirements of ISO 10993-1 “Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within A Risk Management Process.”

Therefore, the performance of the Air Assist device was shown to be at least equivalent to the predicate device and did not raise any new safety or effectiveness questions.

Clinical Testing

No Clinical Testing was required for this product.

Statement of Equivalence

Based on comparison of indications for use, user population, performance testing, mechanical and technological features, the Air Assist device has been shown to be substantially equivalent to the legally marketed predicate device. This device does not raise any new safety or effectiveness questions as compared to the predicate device.