November 13, 2018

Aspire Bariatrics, Inc.
Monica Ferrante, DPA
VP Regulatory & Quality
3200 Horizon Drive, Suite 100
King of Prussia, PA 19406

Re: K182248
Trade/Device Name: Aspire Venting Tube
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: II
Product Code: KNT
Dated: August 15, 2018
Received: August 20, 2018

Dear Monica Ferrante:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jeffrey W. Cooper -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182248

Device Name
Aspire Venting Tube

Indications for Use *(Describe)*
The Aspire Venting Tube is intended for use in adult patients who require gastric decompression.

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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510(k) Summary

Date Prepared: November 13, 2018

Submitter: Aspire Bariatrics, Inc.
3200 Horizon Drive,
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King of Prussia, Pa 19406
Phone 610-590-1577
Fax 610-279-1546

Company Contact: Monica Ferrante, DPA
VP Regulatory & Quality
Email monica.ferrante@aspirebariatrics.com
Phone 484-200-1031

Device Trade Name: Aspire Venting Tube

Classification Name: Gastrointestinal tube and accessories

Classification Regulation: 21 CFR 876.5980

Product Code: KNT

Regulatory Class: II

Review Panel: Gastroenterology and Urology

Common Name: Gastrostomy tube

Predicate Devices: *K103109 Bard Access Systems, Inc., Ponsky Non-Balloon Replacement Gastrostomy Tube (*primary predicate device)
K061021 ConMed Endoscopic, EnTake PEG Standard

Device Description: The Aspire Venting Tube is a gastrostomy tube used to provide secured access to the stomach through the initial placement or a formed stoma. The tube is designed to facilitate decompression.

Indications for Use: The Aspire Venting Tube is intended for use in adult patients who require gastric decompression.

Comparison to Predicates:

Submitter	**Aspire Bariatrics, Inc.**	**Bard Access Systems, Inc** (primary predicate device)	**ConMed Endoscopic**
Product Name	Venting Tube	Ponsky Non-Balloon Replacement Gastrostomy Tube	EnTake PEG Standard
510(k)	TBD	K103109	K061021
Regulation	876.5980	876.5980	876.5980
Product Code	KNT	KNT	KNT
Indications for Use	The Aspire Venting Tube is intended for use in adult patients who require gastric decompression.	For percutaneous placement of a long-term replacement gastrostomy feeding and/or decompression device into an established stoma.	For percutaneous placement of a long-term initial –placement feeding and/or decompression device.
Materials	Medical Grade Silicone	Medical Grade Silicone	Medical Grade Silicone
Radiopacity	Radiopaque w/ BaSO4	Radiopaque	Not Specified
MRI	MR Safe	Not specified	Not Specified
French Size	26Fr	12Fr to 24Fr	14Fr to 24Fr
Stoma Length	25 cm	15 cm	10 cm
Gastric Segment	Internal Bumper and gastric tail with holes to facilitate decompression	Internal Bumper	Internal Bumper (dome)
Placement/ Removal	PEG Pull / Endoscopic Removal	Placement only through existing stoma tract / Traction or Endoscopic Removal	PEG Pull or Push / Traction or Endoscopic Removal
Sterile	Yes EO	Yes - EO	Yes

Technological Characteristics: The Aspire Venting Tube is similar to a standard PEG tube with the addition of a gastric portion to the tube which traverses the stomach and lies upwards towards the fundus. The gastric portion of the tube contains holes along its length to facilitate decompression of the stomach. The Aspire Venting Tube is MR Safe and radiopaque.

The Aspire Venting Tube is comprised of a Gastric segment (15.2cm x 30F) with five venting holes; a Bumper (25mm diameter); and a stoma segment (L: 25cm, OD: 26F, ID: 6mm).

All components are made with materials known for safe and effective long-term use in medical devices, and minor technological differences do not introduce new questions of safety and effectiveness.

Product Material: The Aspire Venting Tube is manufactured from medical grade Silicone

Biocompatibility Testing: The Aspire Venting Tube has been tested for Biocompatibility based on the applicable sections of the ISO 10993-1:2009 series standards.

Performance Testing: Verification and validation of the Aspire Venting Tube to the product specifications and risk mitigation requirements demonstrate that the device is safe and effective for its intended use. Engineering testing, biocompatibility and sterilization validation have all been performed and successfully passed with all requirements met. The performance data detailed in the 510(k) submission demonstrate substantial equivalence to the predicated devices. The following is a list of testing performed:

- EtO Sterilization
- Shelf Life
  - Accelerated
  - Real Time
- Verification Testing
  - Bond Strength (Pull Test)
  - Bumper Pull Through
  - Leak Test
  - Flow Test

Clinical Testing: Not applicable to this device.

Conclusion:

The Aspire Venting Tube is similar to the predicate devices referenced. Differences are minor and do not raise new questions of safety or effectiveness. Therefore, the Aspire Venting Tube is believed to be substantially equivalent to legally marketed gastrostomy devices with regards to intended use, safety and effectiveness.