May 19, 2022

Cardinal Health
Nivedita Namjoshi
Principal Regulatory Affairs Specialist
3651 Birchwood Drive
Waukegan, IL 60085

Re: K213174
Trade/Device Name: Salem Sump Silicone Dual Lumen Stomach Tube with ENFit Connection
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: Class II
Product Code: PIF, FEG
Dated: April 8, 2022
Received: April 11, 2022

Dear Nivedita Namjoshi:

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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213174

Device Name
Salem Sump™ Silicone Dual Lumen Stomach Tube with ENFit™ Connection

Indications for Use *(Describe)*
The Salem Sump™ Silicone Dual Lumen Stomach Tube with ENFit™ Connection is intended for gastric decompression and administration of nutrition, fluids, and medication. The device is intended for patients with age of two and older.

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
Salem Sump™ Silicone Dual Lumen Stomach Tube with ENFit™ Connection

Preparation date:
September 27, 2021

Submitter Information:
Cardinal Health 200, LLC
3651 Birchwood Drive,
Waukegan, IL 60085

Contact Information
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Name of Medical Device:

Trade Name:	Salem Sump™ Silicone Dual Lumen Stomach Tube with ENFit™ Connection
Common Name:	Tubes, gastrointestinal
Classification Name:	Gastrointestinal tube and accessories
Regulation Number:	21 CFR 876.5980
Product Code:	PIF; FEG
Class:	II

Identification of Predicate Device:

510(k) Number	K190923
Device Description	Salem Sump Dual Lumen Stomach Tube with ENFit™ Connection
Submitter	Cardinal Health

Device Description:
The proposed Salem Sump™ Silicone Dual Lumen Stomach Tube with ENFit™ Connection is a dual lumen gastrointestinal enteral access tube made of medical grade silicone. The dual lumen design allows for decompression and administration of fluids within the larger (main) lumen while simultaneously allowing air to enter the secondary (vent) lumen during suctioning. This prevents invagination of the stomach wall into the tube eyelets during gastric decompression. During the period that decompression is needed, delivery of nutritional fluids such as formula, hydration or medication may be delivered through the main catheter lumen. The Salem Sump Silicone Dual Lumen Stomach Tube with ENFit Connection contains an ISO 80369-3 compliant connector tethered to the Y-Shaft of the device. When nutritional fluid delivery is required, the male ENFit connector is inserted into the main lumen. The ENFit connector contains a female cap which helps the connector act as a lumen capping system when feeding or decompression is no longer required. Capping the lumen ends with the ENFit connector and the vent lumen cap helps aid in the prevention of gastric content leakage.

Intended Use/Indications for Use:
The Salem Sump™ Dual Lumen Stomach Tube with ENFit™ Connection is intended for gastric decompression and administration of nutrition, fluids, and medication. The device is intended for patients with age of two and older.

Product Comparison Summary:
The proposed Salem Sump™ Silicone Dual Lumen Stomach Tube with ENFit™ Connection exhibits similar general technological characteristics as the predicate Salem Sump Dual Lumen Stomach Tube with ENFit Connection (K190923) however, they are not the same. Both the predicate and proposed devices are dual lumen tubes intended to be inserted into the stomach through the naso-enteric route for the purpose of gastric decompression and administration of enteral nutrition.

While the proposed Salem Sump™ Dual Lumen Stomach Tube with ENFit™ Connection and the predicate Salem Sump Dual Lumen Stomach Tube with ENFit Connection both have the same features, the major variation between the proposed and the predicate device is in terms of the base material of construction. The proposed device is made of Silicone and predicate device is made of a PVC. Use of Silicone as a base material provides longer use life of 28 days as opposed to the 7 days use life of predicate. The proposed and predicate devices differ in their design due to the respective manufacturing processes required to manufacture the devices with their associated materials of construction. The proposed features an extruded silicone catheter with a silicone Y-port molded to the proximal end. The predicate is extruded (with PVC), but does not feature a molded Y port, instead using a blue "pigtail" which is spliced into the vent lumen of the PVC catheter to create a simulated Y-port.

Non-Clinical Performance Data:
Laboratory testing was completed to support substantial equivalence between the proposed device and the predicate device. The proposed device was evaluated to show compliance to the standards requirements (listed below).

- EN 1615:2000 Enteral feeding catheters and enteral giving sets for single use and their connectors – Design and testing

- EN 1618:1997 Catheters other than intravascular catheters. Test methods for common properties
- ISO 80369-1:2010 Small-bore connectors for liquids and gases in healthcare applications – Part 1: General requirements
- ISO 80369-3:2016 Small-bore connectors for liquids and gases in healthcare applications – Part 3: Connectors for enteral applications
- ISO 80369-20:2015 Small-bore connectors for liquids and gases in healthcare applications – Part 20: Common test methods
- ISO 10993-1:2018 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- ASTM F640-12 Standard Test Methods for Determining Radiopacity for Medical Use.
- ISO 13868: 2002 Catheters - Test Methods for Kinking Of Single Lumen Catheters And Medical Tubing

The following testing was conducted to demonstrate that the device continues to meet the requirements of the product specifications and supports the determination of substantial equivalence.

- Functional Verification
- Occlusion Verification
- Liquid/Fluid Leakage
- Patency Verification
- Tensile Strength
- Resistance to separation from axial load
- Resistance to separation from unscrewing
- Resistance to overriding
- Disconnection by unscrewing
- Stress Cracking
- Dimension verification
- Flow Rate
- Simulated Gastric Indwell
- Biocompatibility Evaluation
- Radiopacity
- Kink Testing
- Shelf – Life (5 years)

The results of the testing demonstrate that the proposed device continues to meet the requirements of the product specifications and supports the determination of substantial equivalence.

Clinical Data:

Clinical evaluations were not relied upon for evidence of safety of effectiveness, or for a determination of substantial equivalence.

Conclusion:

The proposed Salem Sump™ Silicone Dual Lumen Stomach Tube with ENFit™ Connection has the same indications for use, intended use and similar fundamental technological characteristics when

compared to the predicate Salem Sump Dual Lumen Stomach Tube with ENFit Connection (K190923). Verification testing demonstrates that the difference in technological characteristics between the K190923 predicate and the proposed Salem Sump™ Silicone Dual Lumen Stomach Tube with ENFit™ Connection do not raise new questions of safety and efficacy. In addition, test results demonstrate that the proposed device is as safe and effective as the legally marketed predicate device. Based on the above evaluation, the proposed Salem Sump™ Silicone Dual Lumen Stomach Tube with ENFit™ Connection is substantially equivalent to the predicate Salem Sump Dual Lumen Stomach Tube with ENFit Connection (K190923).