November 7, 2019

Cardinal Health
Alexis Erazo
Principal Regulatory Affairs Specialist
777 West Street
Mansfield, MA 02048

Re: K190923
Trade/Device Name: Salem Sump Dual Lumen Stomach Tube with ENFit Connection
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: PIF, FEG
Dated: October 7, 2019
Received: October 8, 2019

Dear Alexis Erazo:

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,

for
Martha W. Betz, Ph.D.
Acting 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K190923

Device Name

Salem Sump™ Dual Lumen Stomach Tube with ENFit™ Connection

Indications for Use *(Describe)*

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.

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™ Dual Lumen Stomach Tube with ENFit™ Connection

Preparation date:
November 4, 2019

Submitter Information:
Alexis Erazo
Principal Regulatory Affairs Specialist
Cardinal Health
777 West Street, Mansfield, MA 02048
Phone: 508.618.3727
Email: alexis.erazo@cardinalhealth.com

Name of Medical Device:

Trade Name:	Salem Sump™ 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	K150711
Device Description	Salem Sump Dual Lumen Stomach Tube with Multi-Functional Port
Submitter	Covidien

Identification of Reference Device:

510(k) Number	K935781
Device Description	Argyle Salem Sump Tube Anti-Reflex Valve Insertion Tray
Submitter	Sherwood Medical Co.

Identification of Reference Device:

510(k) Number	K150084
Device Description	Argyle™ Polyvinyl Chloride (PVC) and Kangaroo™ Polyurethane (PU) Neonatal and Pediatric Feeding Tubes with ENFit connector
Submitter	Covidien

Device Description:
The Salem Sump™ Dual Lumen Stomach Tube with ENFit™ Connection is a double-lumen tube made of PVC used for naso/orogastric drainage and feeding. The larger (main) lumen is

for feeding and drainage, while the smaller lumen draws in outside air to moderate the amount of suction at the drainage eyes. The device contains an ISO 80369-3 compliant ENFit connector which is inserted into the main lumen after decompression is no longer required to administer enteral fluids, including enteral nutrition, hydration and medication. It is a single use device which is provided sterilized via EO sterilization.

The Salem Sump™ Dual Lumen Stomach Tube with ENFit™ Connection is available in the following configurations:

- 6Fr x 24in
- 8Fr x 24in
- 10Fr x 36in
- 12Fr x 48in
- 14Fr x 48in
- 16Fr x 48in
- 18Fr x 48in

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™ Dual Lumen Stomach Tube with ENFit™ Connection has the same intended use, indications for use and similar fundamental technological characteristics and as compared to the predicate Salem Sump Dual Lumen Stomach Tube with Multi-Functional Port (K150711). Verification testing provided demonstrates that the technological characteristics differences to the Salem Sump™ Dual Lumen Stomach Tube with ENFit™ Connection do not raise new questions of safety and efficacy than that of the predicate K150711. The test results demonstrate that the proposed device is as safe and effective as the legally marketed predicate device.

Non-Clinical Performance Data:
Laboratory testing was completed to support substantial equivalence between the modified device and the current device. The modified device was evaluated to show compliance to the standards requirements (listed below) as well as performance characteristics related to the modification of the device.

- 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 10993-1:2009 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

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
- Shelf – Life (2 years)

The results of the testing show that the modified 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™ Dual Lumen Stomach Tube with ENFit™ Connection has the same indications for use, intended use and similar fundamental technological characteristics and as compared to the predicate Salem Sump Dual Lumen Stomach Tube with Multi-Functional Port (K150711). Verification testing demonstrates that the difference in technological characteristics between the K157011 predicate and the proposed Salem Sump™ 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™ Dual Lumen Stomach Tube with ENFit™ Connection is substantially equivalent to the predicate Salem Sump Dual Lumen Stomach Tube with Multi-Functional Port (K150711).