



Food and Drug Administration
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October 8, 2015

Covidien
Wei Zhao, M.D.
Senior Director, Regulatory Affairs
15 Hampshire Street
Mansfield, MA 02048

Re: K150711
Trade/Device Name: Salem Sump™ Dual Lumen Stomach Tube with
Multi-functional Port
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: PIF, FEG
Dated: September 3, 2015
Received: September 4, 2015

Dear Wei Zhao,

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Benjamin R. Fisher -S

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

Indications for Use

510(k) Number (if known)

K150711

Device Name

Salem Sump™ Dual Lumen Stomach Tube with Multi-functional Port

Indications for Use (Describe)

Intended for gastric decompression and delivery of fluids, including irrigation, nutritional supplements, and medication during the time period that gastric decompression is required. The device is intended for patients with age of two-year 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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2.0 510(k) Summary

Salem Sump™ Dual Lumen Stomach Tube with Multi-functional Port

In accordance with section 513(i) of the SMDA and as defined in 21CFR Part 807.92 this summary is submitted by:

Covidien
15 Hampshire Street
Mansfield, MA 02048
Date Prepared: January 18, 2015

a. Contact Person

Wei Zhao
Senior Director, Regulatory Affairs
Covidien
Telephone: (508) 261-8404
Fax: (508) 261-8461

b. Name of Medical Device

Common Name: Tube, double lumen for intestinal decompression and/or intubation

U.S. FDA Classification Product Code: FEG, PIF

U.S. Regulation Description: Gastrointestinal tube and accessories, 21 CFR 876.5980

Proprietary / Trade Name: Salem Sump™ Dual Lumen Stomach Tube with Multi-functional Port

c. Identification of Legally Marketed Device(s)

Next Generation Salem Sump, K040388

d. Device comparison summary

Device Comparison Summary		
	Predicate Device	Proposed Device
Device Name	Next Generation Salem Sump with Multi-port Connector	Salem Sump™ Dual Lumen Stomach Tube with Multi-Functional Port (with ENFit connector)
Intended use	Intended for gastric decompression and delivery of fluids, including irrigation, nutritional supplements, and medication during the time period that gastric decompression is required.	Intended for gastric decompression and delivery of fluids, including irrigation, nutritional supplements, and medication during the time period that gastric decompression is required. The device is intended for patients with age of two-year and older.
Sterility	Sterile by gamma irradiation	Sterile by gamma irradiation and ethylene oxide
Technological Characteristics	The device is a gastric sump tube which utilizes a multifunctional port to allow alternating use for gastric decompression or delivery of fluids, including irrigation, nutritional supplements, and medication. The connection for delivery of fluids supports multiple types of devices and connectors.	The device is a gastric sump tube which utilizes a multifunctional port to allow alternating use for gastric decompression or delivery of fluids, including irrigation, nutritional supplements, and medication. The connection for delivery of fluids is via a male ENFit connector.
Design	The product is a double lumen sump tube available in 5 sizes, 10Fr – 18Fr, and lengths of 36 – 48 inches. The device is equipped with a Multi-functional port to allow alternating use for gastric decompression (via a suction connector) or delivery of fluids, including irrigation, nutritional supplements, and medication via a catheter tip syringe or a feeding set with a step connector.	The product is a double lumen sump tube available in 5 sizes, 10Fr – 18Fr, and lengths of 36 – 48 inches. The device is equipped with a Multi-functional port to allow alternating use for gastric decompression (via a suction connector) or delivery of fluids, including irrigation, nutritional supplements, and medication via a syringe or feeding set equipped with a female ENFit connector.
Materials / Chemical Composition	Sump Tube <ul style="list-style-type: none"> • Polyvinyl chloride 	Sump Tube <ul style="list-style-type: none"> • Polyvinyl chloride

	<p>(PVC)</p> <ul style="list-style-type: none"> • Barium Sulfate • print ink <p>Multi-functional port</p> <ul style="list-style-type: none"> • Polycarbonate • Polyethylene • Polypropylene • Cyanoacrylate adhesive • Silicone rubber • Silicone lubricant • Print ink 	<p>(PVC)</p> <ul style="list-style-type: none"> • Barium Sulfate • print ink <p>Multi-functional port</p> <ul style="list-style-type: none"> • Polycarbonate • Polyethylene • Polypropylene • Cyanoacrylate adhesive • Silicone rubber • Silicone lubricant • Print ink • Copolyester
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e. Discussion of technological differences

The Salem Sump™ Dual Lumen Stomach Tube with Multi-functional Port are intended for gastric decompression and delivery of fluids, including irrigation, nutritional supplements, and medication during the time period that gastric decompression is required. The primary technological difference is the incorporation of the new ENFit connector which is compliant to AAMI/CN3:2014 (PS) Part 3. This connector is part of an industry wide effort to address misconnections by adopting a uniform connector that has been engineered to meet the objective of AAMI/ANSI/ISO 80369-1, small-bore connectors for liquids and gases in healthcare applications - part 1: general requirements. The additional changes implemented in manufacturing technologies are incidental to the primary change, and do not alter device performance.

f. Discussion of Nonclinical testing

- The following risk management activities were executed to identify the potential hazards, evaluate their risks and develop the risk mitigation methods:
 - ENFit connector: Risk management report
 - Proposed device: Design Failure Modes and Effects Analysis (FMEA) and risk analysis.
- Biocompatibility testing in accordance with ISO 10993-1:2009, Biological Evaluation of medical Devices- Part 1: Evaluation and Testing has demonstrated the biological safety of parts of the medical device which may indirectly contact the patient, and is consistent with FDA “Draft Guidance for Industry and FDA staff, Use of international Standard ISO 10993 ‘Biological Evaluation of medical Devices Part 1: Evaluation and Testing,’” issued on April 23, 2013. Similar testing had been conducted for the predicate device.

- Stability testing of the proposed device evaluated the key performance properties of the feeding set after accelerated aging in support of the expiration date which will be applied to the device.
- Usability and human factors testing was conducted as part of the design of the ENFit connector.
- Device tensile properties were evaluated for its durability.
- The following tests were performed to demonstrate the physical and functional performance of the ENFit connector:
 - fluid leakage
 - stress cracking
 - resistance to separation from axial load
 - resistance to separation from unscrewing
 - resistance to overriding
 - disconnection from unscrewing
 - dimensional analysis
- Misconnection assessment of ENFit connector and suctioning port was conducted to prove the incompatibility of the ENFit small bore connector to other medical devices to reduce the risk of misconnection.

g. Clinical testing

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

h. Conclusions

This information provided within this pre-market notification demonstrates that the modified Salem Sump™ Dual Lumen Stomach Tube with Multi-Functional Port with ENFit Connectors is as safe, as effective, and performs as well as or better than the legally marketed device, therefore I find the subject device to be substantially equivalent to the predicate device. The addition of the ENFit connector, which is compliant with AAMI/CN3:2014 (PS) Part 3 is intended to improve device performance by addressing the risk of misconnections.

End of Summary