July 11, 2018

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

Re: K180725
Trade/Device Name: Aspire Introducer Needle
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: II
Product Code: KNT
Dated: June 15, 2018
Received: June 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. 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.

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,

Glenn B. Bell -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)*

K180725

Device Name

Aspire Introducer Needle

Indications for Use *(Describe)*

The Aspire Introducer Needle is intended to be used for guidewire introduction during percutaneous gastrointestinal procedures.

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: March 15, 2018

Submitter: Aspire Bariatrics, Inc.
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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 Introducer Needle

Classification Name: Tubes, Gastrointestinal (and accessories)

Classification Regulation: 21 CFR 876.5980

Product Code: KNT

Regulatory Class: II

Review Panel: Gastroenterology and Urology

Common Name: Introducer Needle

Predicate Devices: K070449 Specialized Health Products, LumiLoc Safety Introducer Needle

K043258 Teleflex Medical, TFX Medical Safety Needle with Introducer

Device Description: The Aspire Introducer Needle is a single use, sterile, non-pyrogenic, disposable product used to provide initial percutaneous access. It is comprised of a stainless steel needle with a plastic sheath to be used in guidewire placement during percutaneous endoscopic procedures. The needle is used once the stomach is insufflated and the site verified through trans-illumination and visualization of finger indentation through the endoscope. The introducer needle is similar in design to other needles currently on the market for the same intended purpose.

The dimensions of this device fall within the range of currently marketed introducer needles with the same intended use, and the materials are similar in that the needle is made from stainless steel and the other components are plastics. The device also incorporates a female luer lock hub in the design, also provided in the predicate devices.

Intended Usage: The Aspire Introducer Needle is intended to be used for guidewire introduction during percutaneous gastrointestinal procedures.

Comparison to Predicates:

Submitter	Aspire Bariatrics, Inc.	Specialized Health Products International, Inc.	Teleflex Medical
Product Name	Introducer Needle	LumiLoc Safety Introducer Needle	Modified TFX Medical Safety Needle with Introducer
510(k)	TBD	K070449	K043258
Regulation	876.5980	876.5980	876.5980
Product Code	KNT	KNT	KNT
Indications for Use	The Aspire Introducer Needle is intended to be used for guidewire introduction during percutaneous gastrointestinal procedures.	The LumiLoc Safety Introducer Needle is intended to be used for percutaneous procedures utilizing a sheathed introducer trocar/needle for guidewire introduction during percutaneous gastrointestinal procedures. LumiLoc Safety Introducer Needle's engineered integral safety guard is passively activated by the clinician upon removal of the trocar/needle from the introducer sheath. The LumiLoc Safety Introducer Needle helps to reduce the risk of accidental trocar/needlestick injuries by locking a safety guard over the trocar/needle tip.	The Modified TFX Medical Safety Needle with Introducer is intended to be used for guidewire introduction during gastrointestinal procedures such as PEG (Percutaneous Endoscopic Gastrostomy), PEJ (Percutaneous Endoscopic Jejunostomy) or other endoscopic gastrointestinal procedures requiring placement of a guidewire.
Materials	Needle: 17 gauge passivated 304 stainless steel Female Luer Needle Hub: Polystyrene Clear Cannula Sheath: High Density Polyethylene with 10% BaSO4 and 1% TiO White	Needle: stainless steel Needle Hub: colored translucent Cannula Sheath: not described	Needle: stainless steel Luer Hub: not described Cannula Sheath: polypropylene (previously High Density Polyethylene)

	Cannula Hub/T Handle: High Density Polyethylene White Protective Sleeve: Low Density Polyethylene Clear	Female Luer Cannula Hub: colored translucent Safety Needle: Seldinger shield	Cannula Hub: not described Safety Needle: not described
Needle Length	10 cm needle plus bevel length of 0.5 cm	Not described	lengths between 2.50" - 4.0" (6.35 – 10.16 cm)
Needle Bevel Indicator	Yes, arrow on Trocar Needle Hub	Yes, bevel up indicator on Trocar Needle Hub	Not described
Needle Gauge	17 Gauge (.058" OD x .048" ID) stainless steel needle with female luer lock hub	Not described	14 – 18 Gauge
Cannula Sheath French size	4 F (.067±.002" ID) 10 cm long cannula sheath with over molded "T" handle	Not described	2F – 6F sizes
Cannula Sheath	Non-peelable	Non-peelable	Non-peelable
Guidewire size	Guidewire < 0.059" (<1.49mm)	Not described	guidewires from 0.015" - 0.052" (0.38 – 1.32mm)
Protective sheath	11.8 cm clear protective sheath (covers and protects cannula and needle prior to use)	Safety Needle Seldinger shield	Safety Needle with passive sharps protection
Sterile	Yes EO	Yes – not specified	Yes

Technological Characteristics:

The Aspire Introducer Needle was subjected to applicable testing to assure reliable design and performance under test parameters. The tests are listed below:

- Needle to Hub bond strength – Test article must meet the specified strength requirements. Test results met predetermined criteria.
- Sheath to Handle bond strength – Test article must meet the specified strength requirements. Test results met predetermined criteria.
- Sterilization – Product is EO sterilized.

Product Materials:

All components are made with materials known for safe and effective use in medical devices. Duration of contact is transient. The Introducer Needle and Sheath are only used during the procedure to provide access through the abdominal wall to the stomach. Once the needle creates the path, it is removed and the cannula sheath remains in place for the guidewire. Once the guidewire is passed through and captured by the endoscope the gastrostomy tube is attached and pulled through the mouth down through the esophagus into the stomach and out through the newly created tract. The sheath is removed with the guidewire.

Needle: 17 gauge passivated 304 stainless steel
Cannula Sheath: High Density Polyethylene with 10% $BaSO_4$ and 1% TiO White
Cannula Hub: High Density Polyethylene White
Locking Hub: Polystyrene Clear
Protective Sleeve: Low Density Polyethylene clear

Biocompatibility Testing:

The Aspire Introducer Needle 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 Introducer Needle 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.

Substantial Equivalence:

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