



Food and Drug Administration
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Silver Spring, MD 20993-0002

May 22, 2015

Summit Access, LLC
c/o Mark Job
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K151076

Trade/Device Name: MicroTaper Needle Introducer Set
Regulation Number: 21 CFR 870.1310
Regulation Name: Vessel Dilator for Percutaneous Catheterization
Regulatory Class: Class II
Product Code: DRE
Dated: April 21, 2015
Received: April 22, 2015

Dear Mark Job:

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

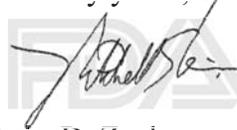
<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go 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,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over a faint, large watermark of the FDA logo.

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K151076

Device Name

MicroTaper™ Needle Introducer Set

Indications for Use (Describe)

The MicroTaper™ Needle Introducer Set is used for percutaneous introduction of a guidewire into the peripheral vasculature. The MicroTaper needle incorporates a blunting mechanism to reduce the risk of accidental needle stick injury.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) SUMMARY

Submitter: Summit Access, LLC
14 Inverness Drive East, Suite H-136
Englewood, CO 80112
(303) 951-8768
Contact: Fred Piazza

Date Prepared: March 31, 2015

Trade/Device Name: MicroTaper™ Needle Introducer Set

Regulation Number: 870.1310
Regulation Name: Vessel dilator for percutaneous catheterization
Regulatory Class: Class II
Product Code: DRE

Predicate Device: Vessel Dilator / Introducer Sheath (510(k) K123445)
Note: one reference device [TFX Medical Safety Needle with Introducer (510(k) K000665)] was used for the sharps injury prevention feature (blunting mechanism) in this submission.

DEVICE DESCRIPTION

The Summit Access Needle Introducer Set consists of:

1 – 0.018 inch (0.46 mm) / 0.035 inch (0.89 mm) Tapered Guidewire, Angled, Nitinol

1 – 21G (0.9 mm) Tapered Needle, 18G (1.27 mm) Max Outside Diameter, Echogenic

The tapered needle consists of a stainless steel cannula with expansion feature and a translucent standard female luer lock hub. Needle is available in lengths of 3, 4, 7, 10, and 15 cm. The needle is used to gain percutaneous access to the vein or artery. The 0.018 inch tapered segment of the guidewire is advanced through the needle allowing confirmation of guidewire placement in the vasculature. The pass-through blunting mechanism is then actuated by twisting hub to needle main body, expanding the needle distal end. An audible confirmation of the actuation and locking confirms the blunting mechanism advances beyond the tip of the needle. The 0.035 inch segment of the guidewire is then advanced through the needle to desired placement. The needle is withdrawn, leaving the guidewire in place.

INDICATIONS FOR USE

The MicroTaper™ Needle Introducer Set is used for percutaneous introduction of a guidewire into the peripheral vasculature. The MicroTaper needle incorporates a blunting mechanism to reduce the risk of accidental needle stick injury.

TECHNOLOGICAL CHARACTERISTICS COMPARED TO PREDICATE DEVICE

Legally marketed vessel dilator for percutaneous catheterization to which substantial equivalence is claimed: Navilyst Medical NMI Coaxial Microintroducer Set (510(k) K123445).

510(k) SUMMARY

ELEMENT OF COMPARISON	SUBJECT DEVICE	CLAIMED SE DEVICE
Device Name	MicroTaper™ Needle Introducer Set	NMI Coaxial Microintroducer Set
Manufacturer Name	Summit Access, LLC	Navilyst Medical, Inc.
510(k) Number	TBD	K123445
Product Code	DRE	DRE
Regulation	21 CFR 870.1310	21 CFR 870.1310
Indications for Use	The MicroTaper™ Needle Introducer Set is used for percutaneous introduction of a guidewire into the peripheral vasculature. The MicroTaper needle incorporates a blunting mechanism to reduce the risk of accidental needle stick injury.	The NMI Coaxial Microintroducer Set is used for the percutaneous introduction of a guidewire into the vascular system.
Labeling	Introducer set labeled for single-use, sterile. Package label includes product identification, lot number, and expiration date. Instructions for use established.	Introducer set labeled for single-use, sterile. Package label includes product identification, lot number, and expiration date. Instructions for use established.
Components	One 21 Gauge Tapered Needle, Echogenic One 0.018” / 0.035” Tapered Guidewire	One 21 Gauge Standard Needle, Echogenic; One Coaxial Sheath/Dilator; One 0.018” Guidewire
Lengths	Needle – 7 cm standard and various other lengths available (3, 4, 10, and 15 cm); Guidewire – 60 cm	Needle – 7 cm; Dilator – 10 cm; Guidewire – 45 cm
Diameters	Needle – 21 Gauge (0.9 mm), Tapered to 18 Gauge (max OD = 1.27 mm); Guidewire – 0.018 inch (0.46 mm) tapered to 0.035 inch (0.89 mm)	Needle – 21 Gauge (0.9 mm); Dilator – 4F or 5F (max OD = 1.73 mm); Guidewire – 0.018 inch (0.46 mm)
Materials (Patient Contacting)	Needle Cannula – Stainless Steel with shrink sleeve; Guidewire – Nitinol with Tungsten Tip and PEEK polymer jacket	Needle Cannula – Stainless Steel; Dilator – Thermoplastic; Guidewire – Nitinol with Tungsten Tip
Proximal Hub	Standard Luer Lock; Translucent	Standard Luer Lock; Translucent
Sharps Injury Prevention	The MicroTaper needle incorporates a blunting mechanism to reduce the risk of accidental needle stick injury. Through-the-lumen blunting safety feature, i.e. blunter advances beyond the tip of the needle.	No sharps injury prevention feature incorporated.

510(k) SUMMARY

Comparison Discussion	<p>The MicroTaper Needle Introducer Set is substantially equivalent to the predicate Navilyst Medical NMI Coaxial Microintroducer Set for the following elements:</p> <ul style="list-style-type: none">- Labeling;- Diameters;- Proximal Hub. <p>The following differences are noted but do not affect substantial equivalence of safety and effectiveness:</p> <ul style="list-style-type: none">- Indications for Use: Subject device specifies use in peripheral vasculature, which is not stated in the predicate device. Both are introducer sets used in the peripheral vasculature. In addition, the subject device incorporates a blunting mechanism to reduce accidental needle stick injury. The sharps protection feature does not affect the intended use as compared to the predicate.- Components: SE device uses a dilator while MicroTaper needle tapers to larger diameter, thus eliminating the need for dilator. Intended use of introduction of guidewire into the vasculature is the same.- Lengths: While 7cm length needle could be used for any peripheral access, the MicroTaper needle lengths available include shorter (3 & 4 cm) for user to more easily manage when a superficial vessel is accessed, such as a radial artery. Longer (10 & 15 cm) may be needed to access a deeper vessel (e.g. morbidly obese patient). The longer guidewire (15cm in additional length) will allow for placement of longer sheaths that are now available in marketplace which can be 45-55cm in length. The length differences do not affect intended use or change the vasculature accessed.- Materials (Patient Contacting): material of MicroTaper guidewire includes PEEK polymer jacket, which was chosen for its lubricity, durability, and flexibility. PEEK is used for other medical device applications. Needle cannula includes shrink sleeve, which is used for needle expansion operation. Device materials have been evaluated to ISO 10993-1 and meets biocompatibility requirements.- Sharps Injury Prevention: the subject device incorporates a blunting mechanism to reduce accidental needle stick injury whereas the SE device does not. The sharps protection feature does not affect the intended use and the design is not new or unique as compared to reference device. The MicroTaper Needle Sharps Injury Prevention feature has been tested to meet FDA Recognized Consensus Standard 6-273 ISO 23908 <i>Sharps injury protection – Requirements and test methods – Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling</i> which encompass the following aspects: Sharps Injury Protection Activation Indication, Sharps Injury Protection Activation, Sharps Injury Protection Locking Mechanism Challenge, and Access To The Sharp In Safe Mode.
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NON-CLINICAL PERFORMANCE DATA

No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for this device. Performance, packaging/labelling, sterilization, and biocompatibility testing of the subject MicroTaper Needle Introducer Set was conducted based on the risk analysis and based on the requirements of recognized and unrecognized international standards and FDA guidance documents.

510(k) SUMMARY

Performance

- Surface Inspection
- Dimensional Inspection
- Hub / Needle Bond Strength
- Hub / Blunting Cannula Bond Strength
- Protective Sheath Puncture
- Needle Penetration
- Conical Fittings with a 6% (Luer) Taper: Gauging, Liquid Leakage, Air Leakage, Separation Force, Unscrewing Torque, Ease of Assembly, Resistance to Overriding, and Stress Cracking
- Guidewire Fracture, Flexing, and Peak Tensile Force
- Guidewire Compatibility
- Corrosion Resistance
- Guidewire Torque Strength, Torqueability, and Tip Flexibility
- Sharps Injury Protection Indication
- Sharps Injury Protection Activation
- Sharps Injury Protection Locking Mechanism Challenge
- Access To The Sharp In Safe Mode
- Other Capabilities – Needle Echogenicity and Guidewire Radiopacity
- Simulated Use

Packaging/Labelling

- Environmental Conditioning and Distribution Simulation
- Package Integrity [Visual Inspection, Bubble Leak Test and Seal Strength Test]
- Stability Testing [Accelerated Aging – Visual Inspection, Bubble Leak and Seal Strength]
- Symbols to be used with medical device labels

Sterilization

- Electron Beam Irradiation Sterilization Qualification using Dose Substantiation Method VDmax25
- Bacterial Endotoxins – LAL Test

Biocompatibility

- Cytotoxicity
- Sensitization
- Irritation or Intracutaneous Reactivity
- System Toxicity (Acute)
- Genotoxicity
- Hemocompatibility
- Pyrogenicity

510(k) SUMMARY

CLINICAL PERFORMANCE DATA

No clinical studies were performed to demonstrate substantial equivalence.

CONCLUSION OF SAFETY AND EFFECTIVENESS

The successful completion of:

- performance tests;
- compliance to biological standard ISO 10993-1; and
- comparison of similarities and differences with predicate device;

demonstrate that the Summit Access MicroTaper Needle Introducer Set is as safe, as effective, and performs as well as or better than the legally marketed predicate device NMI Coaxial Microintroducer Set.