



December 22, 2017

B. Braun Medical Inc.
Kimberly Smith
Sr. Regulatory Affairs Specialist
901 Marcon Blvd.
Allentown, Pennsylvania 18109

Re: K171584

Trade/Device Name: B. Braun Tear-Away Introducer Needle
Regulation Number: 21 CFR 868.5120
Regulation Name: Anesthesia Conduction Catheter
Regulatory Class: Class II
Product Code: BSO
Dated: November 21, 2017
Received: November 21, 2017

Dear Kimberly Smith:

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

 Tina Kiang -
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Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K171584

Device Name

B. Braun Tear-Away Introducer Needle

Indications for Use (Describe)

The B. Braun Tear-Away Introducer Needle is intended to allow for the percutaneous placement of catheters in close proximity to nerves and around or into surgical wound or non-surgical wound sites.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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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B. Braun Medical Inc.
510(k) Premarket Notification
B. Braun Tear-Away Introducer Needle

510(k) Summary

SUBMITTER: B. Braun Medical Inc.
901 Marcon Boulevard
Allentown, PA 18109-9341
610-266-0500

Contact: Kimberly Smith, Sr. Regulatory Affairs Specialist
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E-mail: Kim.smith@bbraun.com

DATE: December 22, 2017

DEVICE NAME: B. Braun Tear-Away Introducer Needle

COMMON NAME: Catheter Introducer

CLASSIFICATION: Class II per 21 CFR 868.5120, Anesthesia conduction catheter
Product Code: BSO
Panel: Anesthesiology

PREDICATE DEVICE: Summit Medical Products, ambIT[®] Introducer
K102460, Class II, BSO, 868.5120

Description

The B. Braun Tear-Away Introducer Needle is a sterile, single-use, disposable device, that consists of a Stainless Steel Needle, Needle Hub, Tear-Away Sheath Hub, Tear-Away Sheath Shaft (tube) and a Protective Guard over the needle.

The B. Braun Tear-Away Introducer Needle is a manually operated device inserted into a patients skin by a surgeon in a clinical hospital setting for the percutaneous introduction of a catheter.

The plastic guard is removed and the B. Braun Tear-Away Introducer Needle is placed through the patient's skin with the bevel tip up. The needle is then withdrawn from the Tear-Away Introducer Sheath and discarded.

The Tear-Away Introducer Needle Sheath remains in the patient to facilitate the placement of an introduction catheter. An introduction catheter is inserted thru the Tear-Away Introducer Needle Sheath and into the patient. Once the introduction catheter is placed to the desired location, the Tear-Away Introducer Needle Sheath is withdrawn by sliding the sheath back towards the hub of the catheter. The Tear-Away Introducer Needle Sheath is then split apart and peeled away from the catheter while holding the hub of the sheath at the T-handle. The Tear-Away Introducer Needle Sheath is then discarded.

Intended Use

The B. Braun Tear-Away Introducer Needle is intended for the percutaneous placement of a catheter.

Indications for Use

The B. Braun Tear-Away Introducer Needle is intended to allow for the percutaneous placement of catheters in close proximity to nerves and around or into surgical wound or non-surgical wound sites.

Substantial Equivalence

Predicate Device - Summit Medical Products, ambIT Introducer (K102460)

The B. Braun Tear-Away Introducer Needle presented in this submission has the identical intended use, similar indications for use, the same principle of operation and the same fundamental scientific technology as the predicate device. They are comprised of the same components and similar materials and meet performance specifications similar to the predicate device.

Characteristic	Proposed B. Braun Tear-Away Introducer Needle	Predicate Device – K102460 ambIT Introducer
Intended Use	Percutaneous placement of a catheter.	Percutaneous placement of a catheter.
Indications for Use	The B. Braun Tear-Away Introducer Needle is intended to allow for the percutaneous placement of catheters in close proximity to nerves and around or into surgical wound or non-surgical wound sites.	The ambIT Introducer products line is intended to allow for the percutaneous placement of catheters in close proximity to nerves and around or into surgical wound or non-surgical wound sites. It may be used to inject or aspirate the introduction area via the luer hub of the needle.
Materials of construction	Needle - Stainless steel (304) Needle hub – polystyrene (clear) Tear-away sheath hub – HDPE with Masterbatch light blue Tear-away sheath tube – HDPE with 10% BaSO ₄ , 1% TiO ₂ Protective Needle Guard – LDPE	Needle - Stainless steel (304), 18 Ga Needle hub – polystyrene (clear) Tear-away sheath hub – HDPE Sheath shaft (tube) – HDPE with 10% BaSO ₄
Summary of nonclinical tests for determination of substantial	<ul style="list-style-type: none"> • Visual • Dimensional Inspection • Luer Compatibility-Gauging • Needle Removal Force • Occlusion • Pressure • Cannula Deflection • Cannula Breakage • Tensile Strength • Associated Device • Stress Cracking • Fluid Leakage by Pressure Decay • Subatmospheric Pressure Air Leakage • Resistance to Separation from Unscrewing • Resistance to Separation from Axial Load • Resistance to Overriding 	<ul style="list-style-type: none"> • Liquid Leakage test • Air Leakage test • Separation Force test • Unscrewing Torque • Ease of assembly • Resistance to Overriding • Stress Cracking • Force to Break • Strength of Union

Characteristic	Proposed B. Braun Tear-Away Introducer Needle	Predicate Device – K102460 ambIT Introducer
Principle of operation	Manual	Manual
Environment of use	For use by a surgeon in hospital environments	Unknown
Sterilization Method	Ethylene Oxide, SAL 10 ⁻⁶	Unknown
Biocompatibility and Contact Duration	<p>External Communicating Device – Tissue/Bone/Dentin, Limited (<24 hrs) Contact Duration device that has a patient exposure of <1hr. Materials meet biocompatibility requirements per ISO 10993-1:2009.</p> <ul style="list-style-type: none"> • Cytotoxicity • Sensitization • Intracutaneous reactivity • Systemic toxicity • Rabbit Pyrogen 	Meets the requirements as set forth in ISO 10993-1.

Testing

The following performance standards were considered when evaluating the functionality of the B. Braun Tear-Away Introducer Needle.

ISO 594-1:1986 - “Conical fittings with a 6% (luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements”

ISO 9626:2016 - “Stainless steel needle tubing for the manufacture of medical devices – Requirements and test methods”

ISO 11070:2014 - “Sterile single-use intravascular catheter introducers, dilators and guidewires”

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

ISO 80369-7:2016 - “Smallbore connectors for liquids and gases in healthcare applications – Part 7: Connectors for intravascular or hypodermic applications”

Results of the testing demonstrate that the proposed device performs similarly to the predicate device and can be used according to its intended use. No clinical testing was performed, as this device does not require clinical studies to demonstrate substantial equivalence with the predicate device.

Conclusion:

The testing performed demonstrates that the B. Braun Tear-Away Introducer Needles are substantially equivalent to the predicate device.