DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 12, 2016

B. Braun Medical Inc.
Ms. Lisa Giaquinto
Sr. Specialist, Regulatory Affairs
901 Marcon Boulevard
Allentown, PA 18109

Re: K153297
Trade/Device Name: Perifix and Contiplex Catheters
Regulation Number: 21 CFR 868.5120
Regulation Name: Anesthesia Conduction Catheter
Regulatory Class: II
Product Code: BSO
Dated: July 8, 2016
Received: July 13, 2016

Dear Ms. Giaquinto:

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,

Tina Kiang -S

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

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)*
Unknown K153297

Device Name
Perifix and Contiplex Catheters

Indications for Use *(Describe)*

The B. Braun Perifix catheters are regional anesthesia catheters intended to provide, via percutaneous administration, continuous and/or intermittent infusion of local anesthetics and analgesics near a nerve for regional anesthesia and pain management during the preoperative, perioperative and postoperative periods associated with general and orthopedic surgery as well as labor and delivery. Routes of administration are epidural. The catheters may remain indwelling for up to 72 hours.

The B. Braun Contiplex catheters are regional anesthesia catheters intended to provide, via percutaneous administration, continuous and/or intermittent infusion of local anesthetics and analgesics near a nerve for regional anesthesia and pain management during the preoperative, perioperative and postoperative periods associated with general and orthopedic surgery. Routes of administration are perineural (peripheral nerve block). The catheters may remain indwelling for up to 72 hours.

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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5. 510(k) SUMMARY

SUBMITTER:	B. Braun Medical Inc. 901 Marcon Boulevard Allentown, PA 18109-9341 610-266-0500 Contact: Lisa Giaquinto, MS, RAC Sr. Specialist, Regulatory Affairs Phone: (610) 596-2354 Fax: (610) 266-4962 E-mail: lisa.giaquinto@bbraun.com
DEVICE NAME:	Perifix and Contiplex Catheters
COMMON OR USUAL NAME: DEVICE	Catheter, Conduction, Anesthetic (An anesthesia conduction catheter is a flexible tubular device used to inject local anesthetics into a patient and to provide continuous regional anesthesia.)
CLASSIFICATION:	Class II, Product Code BSO, 868.5120
PREDICATE DEVICE:	**B. Braun Regional Anesthesia Catheter,** Braun Medical Inc., K042488, Class II, BSO, 868.5120.

DESCRIPTION

The B. Braun Perifix and Contiplex catheters are regional anesthesia catheters intended to provide, via percutaneous administration, continuous and/or intermittent infusion of local anesthetics and analgesics near a nerve for regional anesthesia and pain management. Routes of administration include epidural and perineural (peripheral nerve block). There is no difference in the catheter design of the Perifix catheter when compared to the Contiplex catheter (i.e. the catheters are the same). The only difference between the Perifix and Contiplex catheter is the intended route of administration; Perifix catheters are marketed for use in epidural anesthesia, while Contiplex catheters are marketed for use in peripheral nerve block procedures.

The B. Braun Perifix and Contiplex catheters consists of a hollow polyamide tube with depth markings thermo-diffused into the polyamide tube. The catheters are available in both 19 and 20 Ga. diameters. The Perifix/Contiplex catheters are available in an open-tip configuration (no side ports) as well as a closed-tip configuration (with side ports). The closed-tip catheters have a rounded closed-tip with three side ports for distribution of anesthetics and analgesics.

The catheters include depth markings to identify the depth of insertion during use. The tip of the catheter (proximal to the patient) is also marked to signify the end of the catheter.

INTENDED USE

The B. Braun Perifix catheters are regional anesthesia catheters intended to provide, via percutaneous administration, continuous and/or intermittent infusion of local anesthetics and analgesics near a nerve for regional anesthesia and pain management during the preoperative, perioperative and postoperative periods associated with general and orthopedic surgery as well as labor and delivery. Routes of administration are epidural. The catheters may remain indwelling for up to 72 hours.

The B. Braun Contiplex catheters are regional anesthesia catheters intended to provide, via percutaneous administration, continuous and/or intermittent infusion of local anesthetics and analgesics near a nerve for regional anesthesia and pain management during the preoperative, perioperative and postoperative periods associated with general and orthopedic surgery. Routes of administration are perineural (peripheral nerve block). The catheters may remain indwelling for up to 72 hours.

SUBSTANTIAL EQUIVALENCE

Predicate Device – B. Braun Regional Anesthesia Catheter (K042488)

Device Design

The proposed Perifix and Contiplex catheters are indicated for the same use as the predicate device. In addition, the proposed devices are available in the same gauges and configurations as the predicate device (19-20 Ga., open and closed-tip). The primary differences between the proposed catheters and the predicate catheters are the number of side ports included on the closed-tip version (six in the predicate vs. three in the proposed device), minor dimensional differences, and the materials of construction. The predicate device consists of a co-extruded catheter body, while the proposed device consists of a single polyamide extrusion. In addition, the depth marking ink on the proposed device differs from the predicate device. Despite the differences in design and materials, the proposed catheters meet or exceed the minimum performance requirements of the predicate catheters and do not raise different questions of safety or effectiveness.

Intended Use

The predicate catheters cleared in K042488 are intended to provide, via percutaneous administration, continuous and/or intermittent infusion of local anesthetics and analgesics in the epidural space or near a nerve for regional anesthesia and pain management during the pre-operative, perioperative and postoperative periods associated with general and orthopedic surgery as well as labor and delivery. Routes of administration include epidural and perineural (peripheral nerve block). The proposed catheters are indicated for the same use as the predicate device, however, the intended routes of administration are distinguished by the respective proprietary names: 'Perifix' for the epidural route and 'Contiplex' for the peripheral nerve block route. In addition, the proposed catheters may remain indwelling for up to 72 hours. The indications for use of the predicate catheters cleared in K042488 does not include a limit for indwell time.

Performance Testing

Dimensional and functional performance, including associate device testing (summarized in Table 1) was completed with the proposed catheters. Results of testing demonstrate that the Perifix and Contiplex catheters are substantially equivalent to the predicate device.

Table 1: Performance Test Requirements

Requirement	Test
Dimensional Specifications	Catheters meet dimensional requirements for outer diameter, inner diameter, overall length and depth markings
Functional Testing	Flexibility Markings are legible Catheter tubing is translucent Catheter achieves flow rate requirements Catheter resists kinking Catheter permits flow of fluid when attached to catheter connector Catheter withstands fluid pressure without leakage Catheter withstands minimum tensile force when attached to connector Catheter body withstands minimal tensile force Catheter has sufficient elongation properties
Associate Device Testing	Catheter passes through appropriate size procedural needle without being damaged Catheter passes freely through the threading assist guide Catheter passes freely through sideport valve assembly
Sterilization	-SAL 10^{-6} -EO residual levels met per ISO 10993-7 -LAL bacterial endotoxin levels met per USP <161> an USP <85>

Biocompatibility

The materials of construction of the Perifix and Contiplex catheters are either 1) used in another legally marketed device with the same type and duration of patient contact, and/or 2) are patient contacting and have been evaluated for biocompatibility through testing, which meets and/or exceeds the tests recommended for consideration in ISO 10993-1: 2009, "*Biological Evaluation of Medical Devices* - Part 1: *Evaluation and Testing within a Risk Management Process*." The tests completed with the Perifix and Contiplex catheters are provided in Table 2: *Biocompatibility Tests.*

Table 2: Biocompatibility Tests

Requirement	Test
Biocompatibility and Chemical Testing	Cytoxicity Intracutaneous Reactivity Sensitization Rabbit Pyrogenicity Systemic Toxicity Subchronic Systemic Toxicity Genotoxicity (bacterial reverse mutation, mouse lymphoma, mouse peripheral blood micronucleus) Implantation Chemical Characterization of Materials (Exaggerated Extraction and Simulated Use)

Based on test results, the Perifix and Contiplex catheter materials of construction are considered substantially equivalent to the predicate device.

CONCLUSION:

Results of functional performance and biocompatibility/chemical testing demonstrate that the Perifix and Contiplex catheters do not raise different questions of safety or effectiveness when compared to the predicate device. The Perifix and Contiplex catheters are substantially equivalent to the predicate device.
