September 15, 2023

B. Braun Medical Inc.
Tracy Larish
RA Technical Manager
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K231242
Trade/Device Name: Perifix FX Catheter; Contiplex FX Catheter
Regulation Number: 21 CFR 868.5120
Regulation Name: Anesthesia Conduction Catheter
Regulatory Class: Class II
Product Code: BSO, CAZ
Dated: March 25, 2023
Received: May 1, 2023

Dear Tracy Larish:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Bradley Q. Quinn -S

Bradley Quinn
Assistant Director
DHT1C: Division of Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K231242

Device Name

Perifix FX Catheter;
Contiplex FX Catheter

Indications for Use *(Describe)*

The PERIFIX FX Springwound Epidural Catheter is intended for administration of local anesthetic agents into the epidural space to provide continuous epidural or caudal anesthesia. The catheter should be removed or replaced every 72 hours.

The Contiplex FX catheter is intended to provide continuous and/or intermittent infusion of local anesthetics and analgesics for peripheral plexus anesthesia and pain management. The Contiplex FX catheter 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.

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

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510(k) #: K231242

510(k) Summary

Prepared on: 2023-09-15

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	B. Braun Medical Inc.
Applicant Address	3773 Corporate Parkway Center Valley PA 18034 United States
Applicant Contact Telephone	484-375-9064
Applicant Contact	Mrs. Tracy Larish
Applicant Contact Email	tracy.larish@bbraunusa.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Perifix FX Catheter; Contiplex FX Catheter
Common Name	Anesthesia conduction catheter
Classification Name	Catheter, Conduction, Anesthetic
Regulation Number	868.5120
Product Code	BSO/CAZ

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K991879	Perifix FX catheter (Micor Epiflex)	BSO
K113059	Contiplex FX Continous Nerve Block Set	CAZ

Device Description Summary

21 CFR 807.92(a)(4)

The FX 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. The catheters may remain indwwelling for up to 72 hours. Routes of administration are epidural or perineural (peripheral nerve block (PNB)). The catheter is available in both open and closed tip designs. The open-tip polyamide catheter is intended to facilitate continuous delivery of anesthetic fluid via one opening at the tip, while the closed-tip polyamide catheter facilitates the administration of anesthetic through three sideports. Both catheters have ink markings, which are located in 10 mm increments along the catheter. The ink markings provide a visual indication to the clinician of the depth of catheter insertion. When used according to the conditions listed on the product
labeling, the FX Catheters may remain in a patient while in an MR environment.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The PERIFIX FX Springwound Epidural Catheter is intended for administration of local anesthetic agents into the epidural space to provide continuous epidural or caudal anesthesia. The catheter should be removed or replaced every 72 hours.

The Contiplex FX catheter is intended to provide continuous and/or intermittent infusion of local anesthetics and analgesics for peripheral plexus anesthesia and pain management. The Contiplex FX catheter may remain indwelling for up to 72 hours.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The indications for use are the same for the proposed device as they are for the predicate(s).

Technological Comparison 21 CFR 807.92(a)(6)

The Technological characteristics of the proposed device are the same as the predicate device. There is no change in the design, functional performance, materials or packaging from the proposed device to the predicate(s).

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

MRI testing was performed

Testing supports the device being labeled as MRI Conditional. No changes have been made to the device therefore, the device continues to be safe and effective and performs the same as the predicate device.