July 12, 2024

B. Braun Medical Inc.
Kimberly Smith
Technical Manager I - Regulatory Affairs
824 Twelfth Avenue
Bethlehem, Pennsylvania 18018

Re: K241385
Trade/Device Name: Omnifix Syringe NRFit
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: QEH
Dated: May 15, 2024
Received: May 15, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

For Gang Peng -S

Shruti Mistry
Assistant Director
Division of Drug Delivery and General Hospital Devices
Office of Gastrorenal, ObGyn, General Hospital and Urology 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241385

Device Name
Omnifix Syringe NRFit

Indications for Use *(Describe)*
The B. Braun Omnifix Syringe NRFit is intended for neuraxial use for aspiration/injection of fluids used by healthcare professionals in healthcare facilities.

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

Submitter Information

Name: B. Braun Medical Inc.
Address: 824 Twelfth Avenue
Bethlehem, PA 18018 USA

Contact Person: Kimberly Smith
Title: Technical Manager I – Regulatory Affairs
Tel: (610) 596-2326
Email: kim.smith@bbraunusa.com

Date Prepared: July 12, 2024

Device Name and Classification

Device Trade Name: Omnifix Syringe NRFit
Common Name: Piston Syringe
Classification Name: Piston Syringe With Neuraxial Connector – Epidural, Peripheral, And/Or Indirect Cerebral Spinal Fluid Contact
Regulation Number: 21 CFR §880.5860
Regulation Name: Piston Syringe
Device Class: 2
Product Code: QEH

Predicate Device

510(k) Number: K071459
Device Trade Name: B. Braun Piston Syringes
Common Name: Piston Syringe
Classification Name: Piston Syringe
Regulation Number: 21 CFR §880.5860
Regulation Name: Piston Syringe
Device Class: 2
Product Code: FMF

Reason for Submission

The purpose of this submission is for the modification of the tip of the current B. Braun Medical Inc. Single Use, Piston Syringe (previously cleared under K071459) from the current Luer connections per ISO 594-1 and ISO 594-2 to the new ISO 80369-6 connectors referred to as NRFit. The new syringes with NRFit connectors will be referred to as Omnifix Syringe NRFit and will be supplied in luer slip and luer lock configurations. B. Braun Medical Inc. will continue to market the current B. Braun Medical Inc. Single Use, Piston Syringes with Luer connections for general purpose use, while the new B. Braun Medical Inc. Omnifix Syringe NRFit will be indicated for neuraxial use per ISO 80369-6.

Device Description

B. Braun Medical Inc. Omnifix Syringe NRFit configurations are sterile, single use syringes with ISO 80369-6 NRFit compliant fittings. They are available in 1mL, 3mL, 5mL, 10mL, and 20mL lock and slip configurations. The NRFit tips allow for connections of neuraxial specific applications while reducing the likelihood of misconnections to non-neuraxial devices. The syringe assembly consists of a barrel with a printed graduated scale in milliliters (mL), a stopper and a plunger rod. The plunger rod is yellow to designate a device intended to only connect to ISO 80369-6 compatible devices such as spinal or epidural needles. The plunger rod is pulled back to aspirate fluids or depressed to inject or expel fluids.

Indications for Use

The B. Braun Omnifix Syringe NRFit is intended for neuraxial use for aspiration/injection of fluids used by healthcare professionals in healthcare facilities.

Intended Use

The B. Braun Omnifix Syringe NRFit is intended to be used to inject fluid into, or withdraw fluids from, the body.

Technological Characteristics

The B. Braun Medical Inc. Omnifix Syringe NRFit configurations are equivalent to that of the predicate B. Braun Medical Inc. Omnifix Syringe in intended use, materials and performance characteristics.

The difference between the proposed and predicate B. Braun Medical Inc. Omnifix Syringe is the modification of the tip of the current B. Braun Medical Inc. Single Use, Piston Syringe from the current Luer connections per ISO 594-1 and ISO 594-2 to the new ISO 80369-6 connectors referred to as NRFit. This modification therefore revises the Indications for Use for a neuraxial use application but does not modify the intended use. These differences do not impact the statement of substantial equivalence.

	Proposed Omnifix Syringe NRFit		**Predicate Device (K071459) B. Braun Piston Syringes**	**Differences**
Indications for Use	The B. Braun Omnifix Syringe NRFit is intended for neuraxial use for aspiration/injection of fluids used by healthcare professionals in healthcare facilities.		The Omnifix piston syringes are intended to be used to inject fluid into, or withdraw fluids from, the body.	The proposed device is limited to neuraxial use.
Product Code	QEH		FMF	The proposed device is limited to neuraxial use. Predicate device was for general use.
Intended Use	The B. Braun Omnifix Syringe NRFit is intended to be used to inject fluid into, or withdraw fluids from, the body.		The Omnifix piston syringes are intended to be used to inject fluid into, or withdraw fluids from, the body.	None, Same
Intended User	Healthcare Professionals		Healthcare Professionals	None, Same
Environment of Use	Healthcare Facilities		Healthcare Facilities	None, Same
Syringe components/materials	Barrel	Polypropylene	Polypropylene	None, Same
	Plunger Stopper	Polyisoprene	Polyisoprene	None, Same
	Lubricant	Silicone	Silicone	None, Same
	Plunger Rod	Yellow 1mL Polystyrene / 3, 5, 10, 20 mL Polypropylene	Clear 1mL Polystyrene / 3, 5, 10, 20 mL Polypropylene	Base material is the same. Color is different - change to the plunger from clear to yellow to differentiate the NRFit syringes from the general piston syringes.
Tip Type smallbore connector Functional Testing Summary of ISO 80369-6 compliant nonclinical tests	NRFit lock or slip per ISO 80369-6:2016 • Dimensional Requirements • Fluid leakage requirement • Leakage by pressure decay • Subatmospheric pressure air leakage • Stress cracking • Resistance to separation from axial load • Resistance to separation from unscrewing • Resistance to overriding		Lock or Slip per ISO 594-1:1986 and ISO 594-2:1998 • Gauging • Liquid leakage • Air leakage • Separation force • Unscrewing torque • Ease of assembly • Resistance to overriding • Stress cracking	The proposed device contains a NRFit smallbore connector which is intended for neuraxial use. ISO 80369-6 testing performed to demonstrate safety and effectiveness of the neuraxial smallbore connector for the neuraxial intended use and to confirm substantial equivalence.
Patient Contact category/ Duration	Externally Communicating, Tissue/Bone/Dentin, prolonged exposure		Externally Communicating, Blood Path Indirect, limited exposure	The proposed device is intended for neuraxial use which may have indirect contact with cerebral spinal fluid (CSF). For this reason, Tissue/Bone/Dentin with a longer duration exposure was chosen.
Biocompatibility	Conforms to ISO 10993-1		Conforms to ISO 10993-1	None, Same
Hypodermic Syringe Functional Performance	Conforms to ISO 7886-1		Conforms to ISO 7886-1	None, Same

	Proposed Omnifix Syringe NRFit	**Predicate Device (K071459) B. Braun Piston Syringes**	**Differences**
Neurotoxicity Assessment	No signs of systemic toxicity or neurological impairment from exposure of leachable compounds from the test article.	N/A. Not required previously for predicate device.	The proposed device is intended for neuraxial use which may have indirect contact with CSF. For this reason, a neurotoxicity evaluation was performed.
Pyrogenicity	Spinal limit of 2.15 EU/device	Limit of 20 EU/device	The proposed device is intended for neuraxial use which may have indirect contact with CSF. The proposed devices are therefore tested for endotoxin at the spinal limit of 2.15 EU/device.
Packaging	Individual Unit Package	Individual Unit Package	None, Same
Sterilization Method	Ethylene Oxide	Ethylene Oxide	None, Same
SAL	10^{-6}	10^{-6}	None, Same
Shelf Life	5 Years	5 Years	None, Same

The intended use of the proposed and predicate devices are the same in that both are intended for use by healthcare professionals for aspiration/injection of fluids. However, due to the ISO 80369-6 connector, the Omnifix Syringe NRFit configurations are limited to neuraxial applications. As such, the neuraxial indication, is a subset of the predicate indications for use, which is for general use. Therefore, the above difference in indications for use is not critical to the intended use as the intended use remains for aspiration/injection of fluids. It further does not affect the safety and effectiveness of the device when used as labeled as demonstrated through functional testing. ISO 10993-1 biocompatibility testing, a neurotoxicological assessment, and ISO 80369-6 functional performance testing were conducted to address the changes in indications for neuraxial use and tip design.

Nonclinical Performance Tests

Bench testing performed on the proposed devices supports substantial equivalence. No clinical testing was performed as this device does not require clinical studies to demonstrate substantial equivalence with the predicate device. The following ISO 80369-6 testing has been completed for the proposed device.

- Dimensional Requirements
- Fluid leakage requirement
- Leakage by pressure decay
- Subatmospheric pressure air leakage
- Stress cracking
- Resistance to separation from axial load
- Resistance to separation from unscrewing
- Resistance to overriding

A biocompatibility evaluation was conducted on the subject device per ISO 10993-1:2018. The contact classification is external communicating, indirect contact with blood and tissue with a prolonged use. Based on the evaluation, the following biological tests were conducted:

- Cytotoxicity
- Intracutaneous reactivity
- Sensitization
- Acute systemic toxicity
- Subacute/subchronic systemic toxicity
- Genotoxicity
- Material-mediated pyrogenicity
- Hemolysis

Additionally, the following tests were performed:

- Particulate Matter per USP <788>
- Neurotoxicity assessment

Packaging:
Per ASTM F2096:2011
• Bubble Leak Testing
Per ASTM F88/F88M:2015
• Seal Strength Testing

Summary of Substantial Equivalence

The B. Braun Medical Inc. Omnifix Syringe NRFit configuration is substantially equivalent to the predicate device in intended use, principles of operation, technology, design, materials and performance and are as safe and effective as the predicate devices.