March 5, 2020
B. Braun Medical Inc.
Tracy Larish
Sr. Regulatory Affairs Specialist
901 Marcon Blvd.
Allentown, Pennsylvania 18109

Re: K193101
Trade/Device Name: Omnifix Low Dead Space Luer Lock Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: January 21, 2020
Received: February 3, 2020

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,

For CAPT Alan Stevens
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193101

Device Name
Omnifix® Low Dead Space Luer Lock Syringe

Indications for Use *(Describe)*

The B.Braun Omnifix® Low Dead Space Luer Lock Syringes are intended to be used to inject fluid into, or withdraw fluids from the body.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

5. 510(k) SUMMARY

SUBMITTER INFORMATION:

Name:	B. Braun Medical Inc.
Address:	901 Marcon Boulevard Allentown, PA 18109-9341
Telephone Number:	610-266-0500, ext. 2966
Contact Person:	Tracy Larish, Sr. Regulatory Affairs Specialist
Telephone Number:	(610) 596-2941
Fax Number:	(610) 849-9286
Email:	**tracy.larish@bbraunusa.com**
Date Prepared:	November 8th, 2019

DEVICE NAME:

Device Trade Name:	Omnifix® Low Dead Space Luer Lock Syringes
Common Name:	Piston Syringes
Classification Name:	Piston Syringe, 21 CFR §880.5860: Class II, Product code FMF

PREDICATE DEVICES:

- K071459 B. Braun Omnifix® Piston Syringes

DEVICE DESCRIPTION

The Omnifix® Low Dead Space (LDS) Luer Lock Syringes consist of a graduated hollow barrel and a movable plunger (piston) with a plunger tip. One end of the barrel has a male connector (nozzle), which permits attachment to a female connector (hub) and a needle. The luer lock nozzle has a centric configuration. The Omnifix ® Low Dead Space (LDS) syringes will be available in 1 mL and 2 mL.

INDICATIONS FOR USE:

The B. Braun Omnifix® Low Dead Space Luer Lock syringes are intended to be used to inject fluid into, or withdraw fluids from, the body.

TECHNOLOGICAL CHARACTERISTICS:

The proposed Omnifix® Low Dead Space Luer Lock Syringe is substantially equivalent to the predicate Omnifix® Piston Syringes in terms of indications for use, intended use, general design, functional performance and materials of construction.

The difference between the proposed Omnifix® Low Dead Space Luer Lock Syringe and the predicate do not raise new issues of safety and effectiveness.

	Proposed Device:Omnifix® Low Dead Space (LDS) Luer Lock Syringes	**Predicate Device: Omnifix® piston syringes (K071459)**
Indications	The B.Braun Omnifix® Low Dead Space Luer Lock Syringes are intended to be used to inject fluid into, or withdraw fluids from the body.	**B. Braun Omnifix® Piston Syringes:** The B. Braun Omnifix® Piston Syringes are intended to be used to inject fluid into, or withdraw fluids from, the body.
	Single use only, disposable	Single use only, disposable
Material Composition	Syringe barrel: Polypropylene Syringe plunger:Polypropylene or Polystyrene Plunger tip(piston) Polyisoprene Lubricant: Silicone fluid	Syringe barrel: Polypropylene Syringe plunger: Polystyrene or Polypropylene Plunger tip (piston): Polyisoprene Lubricant: Silicone fluid
Sizes	1 mL, 2 mL	1 mL,2 mL,2.5 mL,3 mL,5 mL,10 mL,20 mL,30 mL, & 50 mL
Syringe tip configurations	Centric tip, luer lock	Syringe tip configurations: centric and eccentric tips, luer slip and luer lock versions (syringes of < 5 mL centric only)
Markings	Graduated scale markings meet requirements of ISO 7886-1:2017	Graduated scale markings meet requirements of ISO 7886-1:1993 and ISO 8537:1991 (E)
Maximum low dead space volume specification	≤ 0.023 mL or 67% less than ISO 7886-1:2017 requirement	Meets ISO 7886-1:2017
Barrel transparency:	translucent	translucent
Sterilization	Ethylene Oxide	Ethylene Oxide

NONCLINICAL TESTING

Bench testing performed on Omnifix® Low Dead Space Luer Lock Syringe demonstrates that the device performs as intended and supports substantial equivalence of the proposed device. No clinical testing was performed as this device does not require clinical studies to demonstrate substantial equivalence with the predicate device. The following testing has been successfully completed for the proposed devices:

- Biocompatibility in accordance with ISO 10993-1:2018
- Sterilization Residual testing in accordance with ISO 10993-7:2008
- Sterilization Validation in accordance with ISO 11135:2014
- Testing in accordance with ISO 7886-1:2017, ISO 80369-7:2016 and ISO 80369-20:2015
- Performance and functional testing to internal specifications

CONCLUSION:

Results of the functional and performance testing conducted on the proposed devices demonstrate that the Omnifix® Low Dead Space Luer Lock Syringes are as safe and effective as the predicate devices. The differences, between proposed devices and predicate devices, do not raise any new issues of safety and effectiveness. Therefore, proposed Omnifix® Low Dead Space Luer Lock Syringe are substantially equivalent to the predicate devices.