May 14, 2022

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

Re: K220626
Trade/Device Name: Introcan Safety IV Catheter
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular catheter
Regulatory Class: Class II
Product Code: FOZ
Dated: April 13, 2022
Received: April 14, 2022

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,

Payal Patel
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220626

Device Name
Introcan Safety® IV Catheter

Indications for Use *(Describe)*
Introcan Safety® IV Catheter is a passive anti-needle stick device to provide venous or arterial access for the infusion of fluids, drugs, and/or blood components, or to facilitate the placement of Vascular Access devices such as guidewires, indwelling central venous catheters, peripherally inserted central catheters, and midline catheters into the vascular system. The catheters may be used with power injectors at a maximum pressure of 325 psi with a luer lock connection only.

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 - K220626

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:	(484) 375-9064
Email:	tracy.larish@bbraunusa.com
Date Prepared:	March 2, 2022

DEVICE NAME:

Device Trade Name:	Introcan Safety® IV Catheter
Common Name:	Catheter, Intravascular, Therapeutic, Short-Term Less Than 30 Days
Classification Name:	Intravascular Catheter, 21 CFR §880.5200: Class II, Product code FOZ

PREDICATE DEVICES:

- K020785 Introcan Safety® IV Catheter, B. Braun Medical, Inc.

DEVICE DESCRIPTION

The Introcan Safety® IV Catheter is a passive needle stick prevention device used for arterial and venous access for the infusion of fluids, drugs and/or blood components or to facilitate the placement of Vascular Access devices such as guidewires, indwelling central venous catheters, peripherally inserted central catheters, and midline catheters into the vascular system. The catheters may be used with power injectors for which the maximum pressure setting is 325 psi. The Introcan Safety IV Catheter is available in 14 - 24 gauge sizes, and both winged and non-winged versions and consists of an over-the-needle, peripheral intravascular catheter made of radiopaque polyurethane, and a passive safety needle-shielding mechanism.

The passive safety needle-shielding mechanism of the Introcan Safety® IV Catheter is located inside the catheter hub. Upon withdrawal of the needle, the safety shield engages as the needle passes through the catheter hub and deploys automatically to shield the needle tip. The safety shield protects during disposal, aiding in the prevention of needlestick injuries. Once the safety shield engages and shields the needle tip, the user is unable to re-insert the needle which aids in the prevention of catheter shearing.

This device may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness for the solution being infused and duration of therapy. The catheters may be used with power injectors with a maximum pressure setting is 325 psi with a luer lock connection only.

INTENDED USE:

The Introcan Safety® IV Catheter is for short term use to sample blood, monitor blood pressure or administer fluids and blood intravascularly or to facilitate the placement of Vascular Access devices such as guidewires, indwelling central venous catheters, peripherally inserted central catheters, and midline catheters into the vascular system.

INDICATIONS FOR USE:

Introcan Safety® IV Catheter is a passive anti-needle stick device to provide venous or arterial access for the infusion of fluids, drugs, and/or blood components, or to facilitate the placement of Vascular Access devices such as guidewires, indwelling central venous catheters, peripherally inserted central catheters, and midline catheters into the vascular system. The catheters may be used with power injectors at a maximum pressure of 325 psi with a luer lock connection only.

TECHNOLOGICAL CHARACTERISTICS:

The proposed Introcan Safety® IV Catheter is substantially equivalent to the predicate Introcan Safety® IV Catheters in terms of indications for use, intended use, general design, functional performance and materials of construction. The materials of the final sterilized device are identical to the currently marketed Introcan Safety® IV Catheter in formulation, processing, and sterilization, and no other chemicals have been added. The Introcan Safety device includes the identical design as the predicate and does not raise any new issues of safety and effectiveness.

The difference between the proposed and predicate Introcan Safety® IV Catheter device do not impact substantial equivalence and are listed below:

- Power injection capabilities were tested to higher pressure injections rates to meet 325psi for all gauge sizes
- Combined the indications for use of the same device to allow one 510(k) to cover the full product offering.
- Instructions for Use revised to update the power injection capabilities, align with the rest of the Introcan product family and utilize an e-IFU.

	Proposed Device Introcan Safety® IV Catheter	**Reference Device(K021094) Introcan Safety® IV Catheter**	**Predicate Device(K020785) Introcan Safety® IV Catheter**	**Comparison**
Indications for Use:	Introcan Safety® IV Catheter is a passive anti-needle stick device to provide venous or arterial access for the infusion of fluids, drugs, and/or blood components, or to facilitate the placement of Vascular Access devices such as guidewires, indwelling central venous catheters, peripherally inserted central catheters, and midline catheters into the vascular system. The catheters may be used with power injectors at a maximum pressure of 325 psi with a luer lock connection only.	The Introcan Safety™ IV Catheter is a passive anti-needle stick device to provide venous or arterial access for the infusion of fluids, drugs, and/or blood components, or to facilitate the placement of Vascular Access devices such as guidewires, indwelling central venous catheters, peripherally inserted central catheters, and midline catheters into the vascular system.	Passive anti-needle stick devices for venous or arterial access for the infusion of fluids, drugs, and/or blood components. 14 - 22 gauge catheters may be used with power injectors for which the maximum pressure setting is 300 psi.	Difference: All sizes to max pressure injection of 325psi. Combines indications for use and adds with a luer lock connection only to align the Introcan product family

	Proposed Device Introcan Safety® IV Catheter	**Reference Device(K021094) Introcan Safety® IV Catheter**	**Predicate Device(K020785) Introcan Safety® IV Catheter**	**Comparison**
Configuration	Single Lumen, Tapered Tip	Single Lumen, Tapered Tip	Single Lumen, Tapered Tip	Same
Material Composition	Catheter Tube: Polyurethane/FEP Catheter Hub: Polypropylene [Needle: Stainless steel [Needle Hub: MABS Safety Clip: Stainless steel	Catheter Tube: Polyurethane or FEP Catheter Hub: Polypropylene [Needle: Stainless steel [Needle Hub: MABS Safety Clip: Stainless steel	Catheter Tube: Polyurethane Catheter Hub: Polypropylene [Needle: Stainless steel [Needle Hub: MABS Safety Clip: Stainless steel	Same
Catheter Gauge Sizes	14ga-24ga	14ga-24ga	14ga-24ga	Same
Catheter length	9/16" (14mm)-2 ½" (64mm)	9/16" (14mm)-2 ½" (64mm)	9/16" (14mm)-2 ½" (64mm)	Same
Gravity Flow Rate	14ga x 32mm (1 1/4") 350 mL/min 14ga x 45mm (1¾") 345mL/min 14ga x 50mm (2") 345 mL/min 16ga x 32mm(1 1/4) 215mL/min 16ga x 50mm (2") 210 mL/min 18ga x 32 mm (1 1/4") 105 mL/min 18ga x 45 mm (1 3/4") 100 mL/min 18ga x 50 mm (2") 95 mL/min 18ga x 64 mm (2½") 85 mL/min 20ga x 25 mm (1") 65 mL/min 20ga x 32 mm (1 1/4") 60 mL/min 20ga x 45mm (1¾") 57 mL/min 20ga x 50 mm (2") 55 mL/min 20ga x 64 mm (2½") 51 mL/min 22ga x 25 mm (1") 35 mL/min 22ga x 45mm (1¾") 26 mL/min 22ga x 64mm (2½") 24 mL/min 24ga x 14mm (9/16") 26 mL/min 24ga x 19 mm(¾") 22 mL/min 24ga x 32 mm (1¼") 17 mL/min !Flow rate as indicated on labeling. Flow rate was not included in original submission	14ga x 32mm (1 1/4") 350 mL/min 14ga x 45mm (1¾") 345mL/min 14ga x 50mm (2") 345 mL/min 16ga x 32mm (1 1/4") 215 mL/min 16ga x 50mm (2") 210 mL/min 18ga x 32 mm (1 1/4") 105 mL/min 18ga x 45 mm (1 3/4") 100 mL/min 18ga x 50 mm (2") 95 mL/min 18ga x 64 mm (2½") 85 mL/min 20ga x 25 mm (1") 65 mL/min 20ga x 32 mm (1 1/4") 60 mL/min 20ga x 45mm (1¾") 57 mL/min 20ga x 50 mm (2") 55 mL/min 20ga x 64 mm (2½") 51 mL/min 22ga x 25 mm (1") 35 mL/min 22ga x 45mm (1¾") 26 mL/min 22ga x 64mm (2½") 24 mL/min 24ga x 14mm (9/16") 26 mL/min 24ga x 19 mm(¾") 22 mL/min 24ga x 32 mm (1¼") 17 mL/min	14ga x 32mm (1 1/4") 350 mL/min 14ga x 45mm (1¾") 345mL/min 14ga x 50mm (2") 345 mL/min 16ga x 32mm (1 1/4") 215 mL/min 16ga x 50mm (2") 210 mL/min 18ga x 32mm (1 1/4 105 mL/min 18ga x 45 mm (1 3/4") 100 mL/min 18ga x 50 mm (2") 95 mL/min 18ga x 64 mm (2½") 85 mL/min 20ga x 25 mm (1") 65 mL/min 20ga x 32 mm (1 1/4") 60 mL/min 20ga x 45mm (1¾") 57 mL/min 20ga x 50 mm (2") 55 mL/min 20ga x 64 mm (2½") 51 mL/min 22ga x 25 mm (1") 35 mL/min 22ga x 45mm (1¾") 26 mL/min 22ga x 64mm (2½") 24 mL/min 24ga x 14mm (9/16") 26 mL/min 24ga x 19 mm(¾") 22 mL/min 24ga x 32 mm (1¼") 17 mL/min !Flow rate as indicated on labeling. Flow rate was not included in original submission	Same
Sterilization	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide	Same
Shelf-Life	5 year	5 year	5 year	Same
Power Injection	14ga-24ga may be used with power injectors at a maximum pressure of 325 psi	None claimed	14-22g may be used with power injectors at a maximum pressure of 300 psi	Bench testing performed which demonstrated that the differences do not raise additional questions of safety and effectiveness

NONCLINICAL TESTING

Bench testing performed on Introcan Safety® IV Catheters 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 completed for the proposed devices:

- Power Injection test for flowrate and device pressure per ISO 10555-1 Section 4.10 AnnexG
- Test for burst pressure under static conditions per ISO 10555-1 Section 4.10 Annex F

CONCLUSION:

Results of the testing conducted on the proposed devices demonstrate that the Introcan Safety® IV Catheters are substantially equivalent to the predicate device and are as safe and effective as the predicate device.