October 25, 2021

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

Re: K213085
Trade/Device Name: Introcan Safety 3 Closed IV Catheter
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: Class II
Product Code: FOZ
Dated: September 17, 2021
Received: September 24, 2021

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)*
K213085

Device Name
Introcan Safety® 3 Closed IV Catheter

Indications for Use *(Describe)*
Introcan Safety® 3 Closed Intravascular Catheter is inserted into a patient's vascular system for short term use to sample blood, monitor blood pressure or administer fluids and blood intravascularly. The catheters may be used with power injectors at a maximum pressure of 325 psi with 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 K213085

SUBMITTER INFORMATION:

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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:	October 13, 2021

DEVICE NAME:

Device Trade Name:	Introcan Safety® 3 Closed IV Catheter
Common Name:	Safety Intravascular Catheter
Classification Name:	Catheter, intravascular, therapeutic, short-term less than 30 day, 21 CFR §880.5200: Class II, Product code FOZ

PREDICATE DEVICES:

- K182870 Introcan Safety® 3 Closed IV Catheter, B. Braun Medical, Inc.

DEVICE DESCRIPTION

The Introcan Safety® 3 Closed IV Catheter consists of an over-the-needle, peripheral intravascular catheter made of radiopaque polyurethane, an integrated bidirectional septum, a stabilization platform, and a passive safety needle-shielding mechanism. Introcan Safety® 3 design is a closed IV catheter since it protects clinicians and patients from blood exposure. Since the needle is withdrawn through a septum that seals after the needle has been removed, blood is thus contained within the Introcan Safety® 3 device. The pressure exerted on the needle as it passes through the septum wipes blood from the needle further reducing potential blood exposure. The Introcan Safety® 3 catheter has an integrated stabilization platform is designed to improve catheter stability while minimizing catheter movement within the vessel. The device controls the flow of blood, aiding in the prevention of blood exposure.

The passive safety needle-shielding mechanism of the Introcan Safety® 3 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 rate of injection based on gauge size and for which the maximum pressure setting is 325 psi with a luer lock connection only.

INTENDED USE:

The Introcan Safety® 3 Closed Intravascular Catheter is for short term use to sample blood, monitor blood pressure or administer fluids and blood intravascularly.

INDICATIONS FOR USE:

Introcan Safety® 3 Closed Intravascular Catheter is inserted into a patient's vascular system for short term use to sample blood, monitor blood pressure or administer fluids and blood intravascularly. The catheters may be used with power injectors at a maximum pressure of 325 psi with luer lock connection only.

TECHNOLOGICAL CHARACTERISTICS:

The proposed Introcan Safety® 3 Closed IV Catheter is substantially equivalent to the predicate Introcan Safety® 3 Closed 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® 3 Closed IV Catheter in formulation, processing, and sterilization, and no other chemicals have been added. The Introcan Safety® 3 device includes the identical septum and clip design as the predicate and does not raise any new issues of safety and effectiveness.

The difference between the proposed and predicate Introcan Safety® 3 Closed IV Catheter device is the power injection capabilities were tested to higher pressure injections rates to meet 325psi for all gauge sizes. Changes were also made to the Instructions for Use to update the power injection capabilities, align with the rest of the Introcan product family and utilize an E-IFU. These differences do not impact the statement of substantial equivalence.

	Proposed Device Introcan Safety® 3 IV Catheter	**Predicate Device(K182870) Introcan Safety® 3 IV Catheter**	**Comparison**
Indications for Use:	Introcan Safety® 3 Closed Intravascular Catheter is inserted into a patient's vascular system for short term use to sample blood, monitor blood pressure or administer fluids and blood intravascularly. The catheters may be used with power injectors at a maximum pressure of 325 psi with a luer lock connection only.	Introcan Safety® 3 Closed Intravascular Catheter is inserted into a patient's vascular system for short term use to sample blood, monitor blood pressure or administer fluids and blood intravascularly. The 18–24 gauge catheters may be used with power injectors at a maximum pressure of 300 psi with a luer lock connection only.	Proposed Includes all sizes to maximum pressure injection of 325psi.
Configuration	Single Lumen, Tapered Tip	Single Lumen, Tapered Tip	Same
Material Composition	Catheter Tube: Polyurethane Catheter Hub: Polypropylene Needle: Stainless steel Needle Hub: MABS Safety Clip: Stainless steel Septum: Silicone or Polyisoprene Rubber Septum Opener: Polyoximethylene Septum Housing: Polypropylene	Catheter Tube: Polyurethane Catheter Hub: Polypropylene Needle: Stainless steel Needle Hub: MABS Safety Clip: Stainless steel Septum: Silicone or Polyisoprene Rubber Septum Opener: Polyoximethylene Septum Housing: Polypropylene	Same
Catheter Gauge Sizes	14ga-24ga	14ga-24ga	Same
Catheter Length	¾" (19mm) –2" (50mm)	¾" (19mm) –2" (50mm)	Same

	Proposed Device Introcan Safety® 3 IV Catheter		**Predicate Device(K182870) Introcan Safety® 3 IV Catheter**		**Comparison**
Gravity Flow Rate	14ga x 32mm (1 1/4")	325 mL/min	14ga x 32mm (1 1/4")	325 mL/min	Same
	14ga x 50mm (2")	310 mL/min	14ga x 50mm (2")	310 mL/min	
	16ga x 32mm (1 1/4")	195 mL/min	16ga x 32mm (1 1/4")	195 mL/min	
	16ga x 50mm (2")	185 mL/min	16ga x 50mm (2")	185 mL/min	
	18ga x 32 mm (1 1/4")	105 mL/min	18ga x 32 mm (1 1/4")	105 mL/min	
	18ga x 45 mm (1 3/4")	100 mL/min	18ga x 45 mm (1 3/4")	100 mL/min	
	20ga x 25 mm (1")	65 mL/min	20ga x 25 mm (1")	65 mL/min	
	20ga x 32 mm (1 1/4")	60 mL/min	20ga x 32 mm (1 1/4")	60 mL/min	
	20ga x 50mm (2")	55 mL/min	20ga x 50mm (2")	55 mL/min	
	22ga x 25 mm (1")	35 mL/min	22ga x 25 mm (1")	35 mL/min	
	24ga x 19 mm (¾")	22 mL/min	24ga x 19 mm (¾")	22 mL/min	
Sterilization	Ethylene Oxide		Ethylene Oxide		Same
Shelf-Life	5 year		5 year		Same
Power Injection	14ga-24ga may be used with power injectors at a maximum pressure of 325 psi		18-24g 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® 3 Closed 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 Annex G
- 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® 3 Closed IV Catheters are substantially equivalent to the predicate device and are as safe and effective as the predicate devices.