June 23, 2022

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

Re: K220756
Trade/Device Name: Introcan Safety 2 IV Catheter
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: Class II
Product Code: FOZ
Dated: May 24, 2022
Received: May 25, 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,

David Wolloscheck, Ph.D.
For 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)*
K220756

Device Name
Introcan Safety® 2 IV Catheter

Indications for Use *(Describe)*
Introcan Safety® 2 IV 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 intravascularly 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) SUMMARY: K220756

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, Regulatory Affairs Project Manager
Telephone Number:	(484) 375-9064
Email:	**tracy.larish@bbraunusa.com**
Date Prepared:	June 22nd, 2022

DEVICE NAME:

Device Trade Name:	Introcan Safety® 2 IV Catheter
Common Name:	Short-Term Less than 30 Days Therapeutic Intravascular Catheter
Classification Name:	Intravascular catheter, 21 CFR §880.5200: Class II, Product code FOZ

PREDICATE DEVICE:

- K213664 Introcan Safety® 2 IV Catheter, B. Braun Medical, Inc.

DEVICE DESCRIPTION

The Introcan Safety® 2 IV Catheter consists of an over-the-needle, peripheral catheter made of radiopaque polyurethane, an integrated septum, and a passive safety needle-shielding mechanism. Introcan Safety® 2 is designed to protect clinicians and patients from blood exposure. During needle withdrawal through a septum that seals after the needle has been removed, blood is thus contained within the Introcan Safety® 2 device. The pressure exerted on the needle as it passes through the septum wipes blood from the needle further reducing potential blood exposure. The passive safety needle-shielding mechanism of the Introcan Safety® 2 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 intravascularly with power injectors for which the maximum pressure setting is 325 psi with a luer lock connection only.

INTENDED USE:

The Introcan Safety® 2 Intravascular Catheter is for short term use to sample blood, monitor blood pressure or administer fluids and blood intravascularly.

INDICATIONS FOR USE:

The Introcan Safety® 2 IV 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 maybe used intravascularly with power injectors at a maximum pressure of 325 psi with a luer lock connection only.

TECHNOLOGICAL CHARACTERISTICS:

The Introcan Safety 2 IV Catheters have the same intended use, the same principle of operation, the identical safety clip and the same fundamental scientific technology as the predicate device.

The differences between the proposed Introcan Safety® 2 IV Catheter and predicate Introcan Safety® 2 IV Catheter are:

- Maximum pressure has been increased to 325psi
- Design changes to the septum and septum opener to maintain blood control during multiple connections

These differences does not raise new issues of safety and effectiveness.

	Proposed Device Introcan Safety® 2 IV Catheter	**Predicate Device(K213664) Introcan Safety® 2 IV Catheter**	**Comparison**
Indications	The Introcan Safety® 2 IV Catheter is for short term use to sample blood, monitor blood pressure, or administer fluids and blood intravascularly and administer fluids subcutaneously. The catheters may be used intravascularly with power injectors at a maximum pressure of 325 psi with a luer lock connection only.	The Introcan Safety® 2 IV Catheter is for short term use to sample blood, monitor blood pressure, or administer fluids and blood intravascularly and administer fluids subcutaneously. The catheters may be used intravascularly with power injectors at a maximum pressure of 300 psi with a luer lock connection only.	Difference: Proposed has maximum pressure injection of 325psi confirmed through bench testing. See Nonclinical Testing.
Configuration	Single Lumen, Tapered Tip, septum with multi blood control	Single Lumen, Tapered Tip, septum with one-time blood control	Difference: Proposed has multi access blood control capabilities confirmed through bench testing. See Nonclinical Testing.
Material Composition	Polyurethane, Polypropylene, Stainless steel, MABS, Polyisoprene, Polyoximethylene	Polyurethane, Polypropylene, Stainless steel, MABS, Polyisoprene, Polyoximethylene	Same
Catheter Sizes	18ga-24ga from 9/16" (14mm) –2" (50mm)	18ga-24ga from 9/16" (14mm) –2" (50mm)	Same
Gravity Flow Rate	18ga x 32 mm: 105 mL/min 18ga x 45 mm: 90 mL/min 20ga x 25 mm: 65 mL/min 20ga x 32 mm: 60 mL/min 20ga X 50 mm: 55ml/min 22ga x 25 mm: 35 mL/min 24ga x 14 mm: 26 mL/min 24ga x 19 mm: 22 mL/min (all flow rates are for both winged and wingless versions)	18ga x 32 mm: 105 mL/min 18ga x 45 mm: 100 mL/min 20ga x 25 mm: 65 mL/min 20ga x 32 mm: 60 mL/min 20ga X 50 mm: 55ml/min 22ga x 25 mm: 35 mL/min 24ga x 14 mm: 26 mL/min 24ga x 19 mm: 22 mL/min (all flow rates are for both winged and wingless versions)	Difference: Flow rate for proposed 18ga x45mm changed and was confirmed through bench testing. See Nonclinical Testing.

	Proposed Device **Introcan Safety® 2 IV Catheter**	**Predicate Device(K213664)** **Introcan Safety® 2 IV Catheter**	**Comparison**
Sterilization	Ethylene Oxide	Ethylene Oxide	Same
Shelf life	1 year	1 year	Same
Bench Testing	Testing according to: • ISO 10555-1:2013 o Air tightness o High pressure(Burst Test) o Flow rate through capillary o Projecting length capillary tip o Catheter hub air aspiration o Power injection • ISO 10555-5 o Dynamic tensile load • Internal Requirement: o Siliconization o Flow rate through metal cannula o Liquid tightness o Force Testing o Blood flashback o Septum opener retention force o Blood exposure o Flushing o Cannula withdrawal angle test	Testing according to ISO 10555-1:2013, Section 4.10, Annex E. Flowrate through capillary, ISO 10555-1:2013 Annex F Burst Pressure and Test for septum opener retention force	Difference: Bench testing demonstrated that the differences do not raise additional questions of safety and effectiveness
Biocompatibility classification	Externally communicating blood path indirect prolonged contact	Externally communicating blood path indirect prolonged contact	Same
MRI labeling	MRI Conditional	MRI Conditional	Same

NONCLINICAL TESTING

Bench testing performed on Introcan Safety® 2 IV Catheters demonstrates that the device performs as intended. No clinical testing was performed as these devices does not require clinical studies to demonstrate substantial equivalence with the predicate device. The following testing has been successfully completed for the proposed devices:

- ISO 10555-1 Intravascular catheters - Sterile and single-use intravascular catheters - Part 1: General requirements
    - Air tightness
    - High pressure(Burst Test)
    - Flow rate through capillary
    - Projecting length capillary tip
    - Catheter hub air aspiration
    - Power injection

- ISO 10555-5 Intravascular Catheters-Sterile and single-use catheters- Part 5: Over-needle peripheral catheters
    - Dynamic tensile load

- Performance and functional testing to internal specifications:
  - Siliconization
  - Flow rate through metal cannula
  - Liquid tightness
  - Force Testing
  - Blood flashback
  - Septum opener retention force
  - Blood exposure
  - Flushing
  - Cannula withdrawal angle test

CONCLUSION:

Results of the testing conducted on the proposed devices demonstrate that the Introcan Safety® 2 IV Catheters are substantially equivalent to the predicate device.