April 1, 2020

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

Re: K192676
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: February 28, 2020
Received: March 2, 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 Tina Kiang, Ph.D.
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)*
K192676

Device Name
Introcan Safety® 2 IV Catheter

Indications for Use *(Describe)*
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 may be used intravascularly with power injectors at a maximum pressure of 300 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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"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."

510(k) SUMMARY – K192676

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:	March 30, 2020

DEVICE NAME:

Device Trade Name:	Introcan Safety® 2 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 DEVICE:

- K182870 Introcan Safety® 3 Closed 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 one directional septum that controls the flow of blood during and after cannulation, and a passive safety needle-shielding mechanism. Introcan Safety® 2 is designed to reduce blood exposure at insertion until first connection of an infusion line or luer device to protect clinicians and patients from blood exposure. During needle withdrawal, the needle is withdrawn 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 300 psi with a luer lock connection only. The devices will be available in 18, 20, 22, and 24-gauge versions with and without a stabilization platform.

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 may be used intravascularly with power injectors at a maximum pressure of 300 psi with a luer lock connection only.

TECHNOLOGICAL CHARACTERISTICS:

The Introcan Safety 2 IV Catheters have the same indications for use, the same intended use, the same principle of operation and the same fundamental scientific technology as the predicate device. They are comprised of the same materials of composition and contain the identical safety clip design as the predicate device

The differences between the proposed Introcan Safety® 2 IV Catheter and predicate Introcan Safety® 3 Closed IV Catheter devices are listed below. These differences do not raise new issues of safety and effectiveness.

- The size offerings are 18-24ga with lengths from 14mm-50mm. Performance of the 14mm Introcan Safety® 2 IV Catheters was confirmed through verification testing to meet the performance requirements of the predicate and proposed device and does not raise concerns of safety and effectiveness when compared to the predicate device.
- The septum provides closed catheter capabilities until the first connection, one-time blood control. The blood control septum of the predicate Introcan Safety® 3 Closed IV Catheter maintains closed catheter capabilities, before and after cannulization and through multiple connections of an infusion device or luer access device. The blood control septum was successfully verified to maintain closed catheter capabilities until first connection using the same verification testing as applied to the predicate device and does not raise new issues of safety and effectiveness when compared to the predicate device.
- A slimmer hub profile which is available with and without securement wings. Performance of the proposed device was confirmed through verification testing to meet the requirements of the predicate and proposed device and does not raise concerns of safety and effectiveness when compared to the predicate device

	Proposed Device Introcan Safety® 2 IV Catheter	**Predicate Introcan Safety® 3 Closed IV Catheter(K182870)**	**Comments**
Indications	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 may be used intravascularly with power injectors at a maximum pressure of 300 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.	Same
Configuration	Single Lumen, Tapered Tip, with one-time blood control septum	Single Lumen, Tapered Tip, with repeat blood control septum	Similar, blood control at insertion providing for closed catheter capabilities until the first connection. See discussion above.
Material Composition	Polyurethane, Polypropylene, Stainless steel, MABS, Polyisoprene,	Polyurethane, Polypropylene, Stainless steel, MABS,	Similar, Polyoximethylene and silicone not required

<table>
<tr><th></th><th>Proposed Device
Introcan Safety® 2 IV Catheter</th><th>Predicate Introcan Safety® 3
Closed IV Catheter(K182870)</th><th>Comments</th></tr>
<tr><td></td><td></td><td>Polyisoprene, Polyoximethylene, silicone</td><td>for the slimmer hub profile, see discussion above.</td></tr>
<tr><td>Catheter Sizes</td><td>18ga-24ga from 9/16 ” (14mm) –2” (50mm)</td><td>14ga-24ga from ¾” (19mm) –2” (50mm)</td><td>Similar, see discussion above.</td></tr>
<tr><td>Safety Clip Conforms to ISO 23908</td><td>Yes</td><td>Yes</td><td>Same</td></tr>
<tr><td>Gravity Flow Rate</td><td><table><tr><td>18ga x 32 mm</td><td>105 mL/min</td></tr><tr><td>18ga x 45 mm</td><td>100 mL/min</td></tr><tr><td>20ga x 25 mm</td><td>65 mL/min</td></tr><tr><td>20ga x 32 mm</td><td>60 mL/min</td></tr><tr><td>20ga X 50 mm</td><td>55ml/min</td></tr><tr><td>22ga x 25 mm</td><td>35 mL/min</td></tr><tr><td>24ga x 14 mm</td><td>26 mL/min</td></tr><tr><td>24ga x 19 mm</td><td>22 mL/min</td></tr></table>(all flow rates are for both winged and wingless versions)</td><td><table><tr><td>14ga x 32 mm</td><td>325 ml/min</td></tr><tr><td>14ga x 50 mm</td><td>310 ml/min</td></tr><tr><td>16ga x 32 mm</td><td>195 mL/min</td></tr><tr><td>16ga x 50 mm</td><td>185 mL/min</td></tr><tr><td>18ga x 32 mm</td><td>105 mL/min</td></tr><tr><td>18ga x 45 mm</td><td>100 mL/min</td></tr><tr><td>20ga x 25 mm</td><td>65 mL/min</td></tr><tr><td>20ga x 32 mm</td><td>60 mL/min</td></tr><tr><td>20ga X 50 mm</td><td>55ml/min</td></tr><tr><td>22ga x 25 mm</td><td>35 mL/min</td></tr><tr><td>24ga x 19 mm</td><td>22 mL/min</td></tr></table></td><td>Same per size</td></tr>
<tr><td>Sterilization</td><td>Ethylene Oxide</td><td>Ethylene Oxide</td><td>Same</td></tr>
<tr><td>Biocompatibility classification</td><td>Externally communicating blood path indirect prolonged contact</td><td>Externally communicating blood path indirect prolonged contact</td><td>Same</td></tr>
<tr><td>Shelf Life</td><td>1 year</td><td>5 year</td><td>Testing on subject device supports 1 year shelf life</td></tr>
<tr><td>MRI Testing</td><td>Yes</td><td>No</td><td>Testing performed in accordance to standards</td></tr>
<tr><td>MRI Test results</td><td>MRI Conditional</td><td>Labeling does not contain MRI Safety Information</td><td>MRI Testing performed on subject device</td></tr>
</table>

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:

- Biocompatibility in accordance with ISO 10993-1 (leveraged from K182870)
- Sterilization Residual testing in accordance with ISO 10993-7
- Sterilization Validation in accordance with ISO 11135
- Testing in accordance with ISO 10555-1, ISO 10555-5, ISO 80369-7, ISO 80369-20, and ISO 9626
- MRI Testing in accordance with ASTM F2052-15, ASTM F2213-17, ASTM F2182-11A, and ASTM F2119-07.
- Performance and functional testing to internal specifications that include:
  - Safety Clip function
  - Liquid Tightness for blood control
    - During cannula Withdrawal
    - After Cannula Withdrawal
  - Flashback
  - Force Testing
  - Shelf life Testing

CONCLUSION:

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