May 15, 2026

B.Braun Medical, Inc.
Tracy Larish
Regulatory Affairs Manager, II
824 Twelfth Ave.
Bethlehem, Pennsylvania 18018

Re: K253235
Trade/Device Name: Introcan Safety® Deep Access XL IV Catheter
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: Class II
Product Code: FOZ
Dated: April 16, 2026
Received: April 16, 2026

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

PAPATYA
KANER -S

Papatya Kaner, Ph.D.
For David Wolloscheck, Ph.D.
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253235

Device Name
Introcan Safety® Deep Access XL IV Catheter

Indications for Use *(Describe)*
Introcan Safety® Deep Access XL IV Catheter is a passive anti-needlestick 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 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.

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

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510(k) SUMMARY: K253235

SUBMITTER INFORMATION:

Name:	B. Braun Medical Inc.
Address:	824 12th Ave Bethlehem, PA 18108
Contact Person:	Tracy Larish, Regulatory Affairs Manager, II
Telephone Number:	(484) 375-9064
Email:	tracy.larish@bbraunusa.com
Date Prepared:	May 14th, 2026

DEVICE NAME:

Device Trade Name:	Introcan Safety® Deep Access XL 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:

- K220626. Introcan Safety® IV Catheter, B. Braun Medical, Inc.

DEVICE DESCRIPTION

The Introcan Safety® Deep Access XL Catheter are sterile, single use, non-pyrogenic, passive anti-needle stick device for short term use (less than 30 days) 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 into the vascular system. The catheters may be used with power injectors for which the maximum pressure setting is 325 psi with the use of a luer lock connection between the Introcan Safety® Deep Access XL Catheter and the power injector. The Introcan Safety® Deep Access XL IV Catheter(s) consists of an insertion platform surrounding an over-the-needle, peripheral intravascular catheter made of radiopaque polyurethane, and a passive safety needle-shielding mechanism available in 18, 20 and 22 Gauge with lengths from 80-100 mm (3 1/6 -4 inch)

The cannula insertion process may be supported by Ultrasound guidance. The device is placed by grasping the insertion platform (The stabilizer embraces and stabilizes the cannula during initial puncture, also provides the benefit of non-touch technique which allows the user to insert the product into patient vessel without direct contact to the catheter. The spring ribbons are inserted into the stabilizer to facilitate automated opening of the stabilizer arms during cannulation. The perforated label applied on top of the stabilizer arms serves as indicator of the direction of cannulation, inserting the needle to gain access. Upon withdrawal of the needle, the safety shield (located inside the catheter hub) engages as the needle passes through the catheter hub and deploys the safety shield automatically to

shield the needle tip. 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. The safety shield also protects during disposal, aiding in the prevention of needlestick injuries.

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® Deep Access XL Intravascular Catheter is for short term use to sample blood, monitor blood pressure or administer fluids and blood intravascularly.

INDICATIONS FOR USE:

Introcan Safety® Deep Access XL IV Catheter is a passive anti-needlestick 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 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 Introcan Safety® Deep Access XL IV Catheters have the same intended use, indications for 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® Deep Access XL IV Catheter and predicate Introcan Safety® IV Catheter does not raise new issues of safety and effectiveness and are listed below and in the substantial equivalence table:

- Streamlined Indications for use
- Longer catheter length of 80-100 mm (3 1/6 -4 inch)
- Longer protective cap to accommodate longer lengths.
- Insertion platform added to aid in insertion
- Minor change in packaging to accommodate the longer length.
- Shelf-Life testing for 3 years

Substantial equivalence Table

<table>
<tr><th></th><th>Proposed Device(K253235)
Introcan Safety® Deep Access XL IV Catheter</th><th>Predicate Device(K220626)
Introcan Safety® IV Catheter</th><th>Comparison</th></tr>
<tr><td>Indications for Use:</td><td>Introcan Safety® Deep Access XL 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 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.</td><td>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.</td><td>Indications for use were streamlined to remove examples of vascular access devices that historically have been called out as vascular access devices are known</td></tr>
<tr><td>Configuration</td><td>Single Lumen, Tapered Tip, insertion platform</td><td>Single Lumen, Tapered Tip</td><td>Insertion platform added</td></tr>
<tr><td>Material Composition of patient contacting components</td><td>Catheter Tube: Polyurethane
Catheter Hub: Polypropylene
Needle: Stainless steel
Needle Hub: MABS
Safety Clip: Stainless steel</td><td>Catheter Tube: Polyurethane/FEP
Catheter Hub: Polypropylene
Needle: Stainless steel
Needle Hub: MABS
Safety Clip: Stainless steel</td><td>Catheter tube available in PUR only</td></tr>
<tr><td>Catheter Gauge Sizes</td><td>18ga-22ga</td><td>14ga-24ga</td><td>Same</td></tr>
<tr><td>Catheter Length</td><td>80mm (3 1/6”) -100mm(4”)</td><td>9/16” (14mm) –2 ½ ” (64mm)</td><td>Additional length</td></tr>
<tr><td>Gravity Flow Rate</td><td><table><tr><td>18ga x 80mm (3 1/6”)</td><td>85 mL/min</td></tr><tr><td>18ga x 100mm (4”)</td><td>78 mL/min</td></tr><tr><td>20ga x 80mm (3 1/6”))</td><td>50 mL/min</td></tr><tr><td>20ga x 100mm (4”)</td><td>45 mL/min</td></tr><tr><td>22g x 80mm (3 1/6”)</td><td>23 mL/min</td></tr></table></td><td><table><tr><td>14ga x 32mm (1 1/4”)</td><td>350 mL/min</td><td>20ga x 32 mm (1 1/4”)</td><td>60 mL/min</td></tr><tr><td>14ga x 45mm (1 ¾”)</td><td>345mL/min</td><td>20ga x 45mm (1 ¾”)</td><td>57 mL/min</td></tr><tr><td>14ga x 50mm (2”)</td><td>345 mL/min</td><td>20ga x 50 mm (2”)</td><td>55 mL/min</td></tr><tr><td>16ga x 32mm (1 1/4”)</td><td>215 mL/min</td><td>20ga x 64 mm (2 ½”)</td><td>51 mL/min</td></tr><tr><td>16ga x 50mm (2”)</td><td>210 mL/min</td><td>22ga x 25 mm (1”)</td><td>35 mL/min</td></tr><tr><td>18ga x 32 mm (1 1/4”)</td><td>105 mL/min</td><td>22ga x 45mm (1 ¾”)</td><td>26 mL/min</td></tr><tr><td>18ga x 45 mm (1 3/4”)</td><td>100 mL/min</td><td>22ga x 64mm (2 ½”)</td><td>24 mL/min</td></tr><tr><td>18ga x 50 mm (2”)</td><td>95 mL/min</td><td>24ga x 14mm (9/16“)</td><td>26 mL/min</td></tr><tr><td>18ga x 64 mm (2 ½”)</td><td>85 mL/min</td><td>24ga x 19 mm (¾”)</td><td>22 mL/min</td></tr><tr><td>20ga x 25 mm (1”)</td><td>65 mL/min</td><td>24ga x 32 mm (1 ¼”)</td><td>17 mL/min</td></tr></table></td><td>Same test performed results based on size</td></tr>
<tr><td>Sterilization</td><td>Ethylene Oxide</td><td>Ethylene Oxide</td><td>Same</td></tr>
<tr><td>Shelf-Life</td><td>3 year</td><td>5 year</td><td>Difference: Testing done to 3 years</td></tr>
<tr><td>Power Injection</td><td>maximum pressure of 325 psi</td><td>maximum pressure of 325 psi</td><td>Same</td></tr>
<tr><td>MRI labeling</td><td>MRI Conditional</td><td>MRI Conditional</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>Bench Testing</td><td>Testing according to:
• ISO 10555-1:2013Annex F, G
o Flow rate through capillary
o Power injection
o Burst Pressure
Internal Requirement:
o Projecting Length Capillary tip
o Pull strength protective cap
o Stabilizer arms opening distance
o Arms opening force
o Kink Resistance Testing</td><td>Testing according to ISO 10555-1:2013, Section 4.10, Annex E. Flowrate through capillary, ISO 10555-1:2013 Annex F Burst Pressure</td><td>Difference:
Bench testing demonstrated that the differences do not raise additional questions of safety and effectiveness</td></tr>
</table>

NONCLINICAL TESTING:

Bench testing performed on Introcan Safety® Deep Access XL 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*
  - Flow rate through capillary
  - Power injection
  - Burst Pressure
- Performance and functional testing to internal specifications:
  - Projecting length capillary tip
  - Pull Strength protective cap
  - Stabilizer arms opening distance
  - Arms opening force
  - Kink Resistance Testing
- Package Integrity testing
  - ISO 11607-1 *Packaging for terminally sterilized medical devices-Part 1: Requirements for materials sterile barrier systems and packaging systems*
    - Visual inspection for cleanliness - product
    - Visual inspection for printing (non- variable data and variable data)
    - Width of sealing (self-sealing side)
  - ASTM F2096-11 *Standard Test Methods for Detecting gross Leaks in Packaging by Internal Pressurization (Bubble Test)*
    - Visual inspection for cleanliness – seal
    - Bubble test (test of packaging with product)
  - ASTM F88-23 *Standard Test Method for Seal Strength of Flexible Barrier Materials*
    - Tensile strength of the longitudinal seam (self-sealing)
  - ASTM F1929-23 *Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration*
    - Intactness of seal (Blue dye test)

CONCLUSION:

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