



Food and Drug Administration  
10903 New Hampshire Avenue  
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April 28, 2017

B. Braun Melsungen Ag  
% Kimberly Smith  
Senior Regulatory Affairs Specialist  
B. Braun Medical Inc.  
901 Marcon Blvd.  
Allentown, Pennsylvania 18109

Re: K163358  
Trade/Device Name: Introcan Safety<sup>®</sup> 3 Closed IV Catheter  
Regulation Number: 21 CFR 880.5200  
Regulation Name: Intravascular Catheter  
Regulatory Class: Class II  
Product Code: FOZ  
Dated: March 29, 2017  
Received: March 30, 2017

Dear Kimberly Smith:

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. 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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and Part 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,

 Tina  
Kiang -S

Tina Kiang, Ph.D.  
Acting Director  
Division of Anesthesiology,  
General Hospital, Respiratory,  
Infection Control, and Dental Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K163356

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.

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                    K163358**

**SUBMITTER:**                    B. Braun Medical Inc.  
901 Marcon Boulevard  
Allentown, PA 18109-9341  
610-266-0500  
Contact: Kimberly Smith, Sr. Regulatory Affairs Specialist

**DATE:**                            April 28, 2017

**DEVICE NAME:**                Introcan Safety® 3 Closed IV Catheter

**COMMON OR  
USUAL NAME:**                Safety Intravascular Catheter

**DEVICE  
CLASSIFICATION:**            Class II per 21 CFR §880.5200  
Intravascular Catheter  
Product Code FOZ

**PREDICATE  
DEVICE:**                        Introcan Safety® 3 Closed IV Catheter  
B. Braun Medical Inc., K111236  
General Hospital, Class II, per 21 CFR §880.5200  
Intravascular Catheter

**SUBJECT OF 510(K):** Addition of 16G Catheter Size to Product Portfolio

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**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 Closed IV Catheter design is described as 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 Closed IV Catheter has an integrated stabilization platform is designed to improve catheter stability while minimizing catheter movement within the vessel.

The passive safety needle-shielding mechanism of the Introcan Safety® 3 Closed 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.

The 16ga includes the incremental changes to the predicate since clearance that were implemented in accordance with 21 CFR 820.30. The changes included an alternative septum material, establishment of a 5 year shelf life, instructions for use update to include precise flow rates, and product enhancements.

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.

#### **INTENDED USE:**

The 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.

#### **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.

#### **SUBSTANTIAL EQUIVALENCE:**

##### ***Technological Characteristics***

The Introcan Safety® 3 Closed IV Catheter 16ga x 1-1/4 in. (32mm) and 16ga x 2 in. (50mm) sizes has a slightly modified indications to remove the regulatory language (< 30 days) and the reference to additional sizes in the product family which are not part of this review. These minor differences between the Indications for Use do not change the intended use of the predicate devices or raise different questions of safety and effectiveness.

The subject device is similar in the principals of operation and technological characteristics as the predicate device. The subject devices are constructed of the same materials, are manufactured, and sterilized utilizing the same processes.

##### ***Performance Testing***

The Introcan Safety® 3 Closed IV Catheter 16ga x 1-1/4 in. (32mm) and 16ga x 2 in. (50mm) sizes were subjected to functional and performance testing to demonstrate that the devices perform as intended. The following testing was performed:

- Dynamic Tensile
- Air Tightness

- Flow Rate
- Projecting/Trim Length Capillary Tip
- Liquid Tightness
- Withdrawal Force
- Clip Drag Force
- Pull Strength
- Blood Flashback
- Clip Function

**Substantial Equivalence Comparison**

<b>Parameter</b>	<b>Proposed Device Introcan Safety® 3 Closed IV Catheter</b>	<b>Predicate Device Introcan Safety® 3 Closed IV Catheter 510(k) K111236</b>
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.	Introcan Safety®3 Closed Intravascular Catheter is inserted into a patient's vascular system for short term use (less than 30 days) to sample blood, monitor blood pressure or administer fluids and blood intravascularly. The 18-22 gauge catheters may be used with power injectors at a maximum pressure of 300 psi with a luer lock connection only.
Intended Use	Prescription Use The 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.	Prescription Use The Introcan Safety® 3 Closed Intravascular Catheter is inserted into a patient's vascular system for short term use (less than 30 days) to sample blood, monitor blood pressure or administer fluids and blood intravascularly.
Configuration	Single Lumen, Tapered Tip	Single Lumen, Tapered Tip
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 Septum Opener: Polyoximethylene Septum Housing: Polypropylene
Catheter Gauge Sizes	16ga	18ga-24ga
Catheter Length	1-1/4 in. (32mm) – 2 in. (50mm)	¾ in. (19mm) – 1-3/4 in. (45mm)
Gravity Flow Rate	16ga x 32mm 95 mL/min 16ga x 50mm 105 mL/min	18ga x 45 mm 95 mL/min 18ga x 32 mm 105 mL/min 20ga x 32 mm 60 mL/min 20ga x 25 mm 65 mL/min 22ga x 25 mm 35 mL/min 24ga x 19 mm 22 mL/min
Sterilization	Ethylene Oxide	Ethylene Oxide
Shelf-Life	5 years	2 years

Results of the performance testing demonstrate that the proposed devices perform similarly to the predicate device. No clinical testing was performed, as this device does not require clinical studies to demonstrate substantial equivalence with the predicate device.

**CONCLUSION:**

Results of functional and performance testing conducted on the proposed devices demonstrate that the Introcan Safety® 3 Closed IV Catheter 16ga x 1-1/4 in. (32mm) and 16ga x 2 in. (50mm) sizes are safe and perform as intended. The differences between the subject devices and the predicate do not raise different questions of safety and effectiveness.