March 7, 2019

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

Re:  K182870
   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:  February 4, 2019
   Received:  February 8, 2019

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Sapana Patel-S

for 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

Introcan Safety® 3 Closed 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 18-24-gauge catheters may be used with power injectors at a maximum pressure of 300 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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Paperwork Reduction Act (PRA) Staff
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SUBMITTER INFORMATION:

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         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: February 4th, 2019

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:

- K111236 Introcan Safety® IV Catheter, B. Braun Medical, Inc.
- K163358 Introcan Safety® 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 18-24 gauge catheters may be used with power injectors with a rate of injection based on gauge size and for which the maximum pressure setting is 300 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 18-24-gauge catheters may be used with power injectors at a maximum pressure of 300 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 product family in formulation, processing, and sterilization, and no other chemicals have been added.

The differences between the proposed and predicate Introcan Safety® 3 Closed IV Catheter devices are listed below. These differences, do not impact the statement of substantial equivalence.

- line extension to the size offerings to include an additional length for the 20Ga in a 50mm size and a 14 Ga. x 1-1/4” (32mm) and 14 Ga. x 2” (50mm)
- power injection capabilities are extended to the 24 Ga. device. The 16Ga. and the proposed 14 Ga. devices are not indicated for power injection.

Changes were made to the Instructions for Use to update the gauge sizes cleared for power injection and to reflect the verbiage of the most recently cleared device. These differences do not impact the statement of substantial equivalence.

The proposed Introcan Safety® 3 Closed IV Catheter 18-24 gauge devices include the identical septum, clip design and injection capabilities as the predicates and do not raise any different issues of safety and effectiveness.

<table>
<thead>
<tr>
<th>Proposed Device</th>
<th>Predicate Device(K163358)</th>
<th>Predicate Device(K111236)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introcan Safety® 3 IV Catheter</td>
<td>Introcan Safety® 3 Closed Intravascular Catheter</td>
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</tr>
<tr>
<td>Configuration</td>
<td>Single Lumen, Tapered Tip</td>
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</tbody>
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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:

- Biocompatibility in accordance with ISO 10993-1
- Sterilization Residual testing in accordance with ISO 10993-7
- Sterilization Validation 11135-1
- Testing in accordance with ISO 10555-1 and ISO 10555-5
- Performance and functional testing to internal specifications that include:
  - Safety Clip function
  - Liquid Tightness
  - Flashback

CONCLUSION:

Results of the functional and performance testing conducted on the proposed devices demonstrate that the Introcan Safety® 3 Closed IV Catheters is as safe and effective as the predicate devices. The proposed Introcan Safety® 3 Closed IV Catheter are substantially equivalent to the predicate devices.