DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

B. Braun Medical Incorporated
Ms. Nancy Skocypec
Regulatory Affairs Manager
901 Marcon Boulevard
Allentown, Pennsylvania 18109

November 12, 2015

Re: K150800
Trade/Device Name: Valved Safety Centesis Catheter
Regulation Number: 21 CFR 878.4200
Regulation Name: Introduction/drainage catheter and accessories
Regulatory Class: Class I
Product Code: GCB
Dated: October 14, 2015
Received: October 20, 2015

Dear Ms. Skocypec:

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); 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), 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 yours,

Joshua C. Nipper -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K150800

Device Name

Valved Safety Centesis Catheter

Indications for Use *(Describe)*

The Valved Safety Centesis Catheter is indicated for the therapeutic or diagnostic aspiration of fluids from body cavities.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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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5. 510(k) SUMMARY

Date:	November 10, 2015
Submitter:	B. Braun Medical Inc.
Address:	901 Marcon Boulevard Allentown, PA 18109-9341
Phone number:	610-266-0500
Contact:	Nancy Skocypec
Phone:	(610) 596-2796
Fax:	(610) 266-4962
E-mail:	nancy.skocypec@bbraun.com
Trade name:	Valved Safety Centesis Catheter
Common name:	Centesis Catheter
Product Code:	GCB, Needle, Catheter
Regulation:	21 CFR 878.4200, Drainage Catheter, Class II
Predicate Device:	Paracentesis Catheter, Allegiance Healthcare Corporation, K974146
Reference device:	Introcan Safety 3, B. Braun Medical Inc., K111236

Description:

The Valved Safety Centesis Catheter is a drainage, centesis catheter with a self sealing valve and a passive safety needle-shielding feature. The catheter is designed with drainage holes located around the distal tip of the catheter to facilitate the drainage of fluid. The catheter surface and tapered end is designed for smooth transition through the tissue, while the inner surface is designed for easy retraction of the insertion needle. The insertion needle comes with a vent plug that allows air to exit and does not allow fluid to exit. The echogenic needle tip provides a guidance for proper catheter placement using ultrasound. The needle hub is clear and locks within the catheter hub. The catheter is radiopaque and can be visualized using fluoroscopy. The hub of the catheter contains a luer adapter to facilitate attachment of drainage collection devices and a bevel indicator for needle bevel orientation reference. The device is provided individually packaged sterile.

A drainage catheter under 21 CFR 878.4200 is normally classified as Class I exempt; however, this device has a sharps injury prevention feature. According to the FDA Guidance, "Medical Devices with Sharps Injury Prevention Features", devices with sharps injury prevention features are Class II devices subject to 21 CFR Part 820 Quality System Regulation. Therefore, under 21 CFR 878.9, a premarket notification is required before introducing this catheter into interstate commerce for commercial distribution.

Indications for Use:
The Valved Safety Centesis Catheter is indicated for the therapeutic or diagnostic aspiration of fluids from body cavities.

Substantial Equivalence:

Technical Characteristics
The Valved Safety Centesis Catheter has the following similarities to the predicate device:

- Intended use
- Indications for use
- Catheter-over-the-needle design
- Principle of operation
- Self sealing valve
- Radiopaque catheter

The differences between the predicate and subject device include a sharps injury prevention feature, catheter material composition and attached components.

Performance Testing
The proposed Valved Safety Centesis Catheter was subjected to functional and performance testing to demonstrate that the device performs as intended.

The following testing was performed:

- Visual Inspection
- Radio-detectability
- Echogenicity
- Flow rate
- Occlusion
- Tensile strength
- Pressure testing
- Penetration force
- Safety feature verification

Biocompatibility Testing
Biocompatibility testing and chemical characterization was completed considering the recommendations defined in ISO 10993-1. The biocompatibility testing verified that no new issues of biocompatibility have been introduced with the proposed devices and therefore support the biological safety of the materials of composition.

Results of performance and biocompatibility testing demonstrate that the proposed device performs similarly to the predicate device and can be used safely and effectively according to its intended use. No clinical testing was performed as this device does not require clinical studies to demonstrate substantial equivalence with the predicate device.

Conclusion:

Results of testing conducted on the proposed device demonstrate that the Valved Safety Centesis Catheter is safe and effective when used in accordance with its intended use. The differences, between subject device and predicate device, do not raise any new issues of safety and effectiveness. The Valved Safety Centesis Catheter is therefore substantially equivalent to the predicate device.