



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

December 2, 2015

B. Braun Medical, Inc.
Ms. Tracy Maddock
Senior Regulatory Affairs Specialist
901 Marcon Boulevard
Allentown, Pennsylvania 18109

Re: K150787
Trade/Device Name: Universal Spike
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: LHI
Dated: October 28, 2015
Received: October 29, 2015

Dear Ms. Maddock:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

 Tina
Kiang -S

for Erin I. Keith, M.S.

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)

K150787

Device Name

Universal Spike

Indications for Use (Describe)

For the transfer of solutions from one container to another.

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)



*B. Braun Medical Inc.
510(k) Premarket Notification
Universal Spike*

5. 510(k) Summary K150787

SUBMITTER: B. Braun Medical Inc.
901 Marcon Boulevard
Allentown, PA 18109-9341
610-266-0500

Contact: Tracy Maddock, RAC
Sr. Regulatory Affairs Specialist
Phone: (610) 596-2545
Fax: (610) 266-4962
E-mail: Tracy.Maddock@bbraun.com

DATE: December 2, 2015

DEVICE NAME: Universal Spike

**COMMON OR
USUAL NAME:** IV Fluid Transfer Set

**DEVICE
CLASSIFICATION:** Class II per 21 CFR 880.5440
Intravascular Administration Set, product code LHI
Classification Panel: General Hospital

PREDICATE DEVICES: B. Braun Dispensing Pin with One-Way Valve, K943181

DESCRIPTION:

The B. Braun Universal Spike is a sterile, single use, disposable fluid transfer device consisting of a closure-piercing component capable of piercing and penetrating the closure of a fluid container, an air-inlet component which allows the dispensing from both rigid and pressure collapsible dispensing containers, and a distal female luer lock adapter which provides access for the attachment of a syringe or fluid transfer set. The closure-piercing component and luer lock adapter are covered by protective caps which prevent contamination of the device until its point of use.

**INTENDED USE
INDICATIONS FOR USE:**

For the transfer of solutions from one container to another.

B. Braun Medical Inc.
 510(k) Premarket Notification
 Universal Spike

SUBSTANTIAL EQUIVALENCE:

The Universal Spike is substantially equivalent to the B. Braun Dispensing Pin with One-Way Valve (K943181).

Comparison of Technological Characteristics with the Predicate Device

The proposed device has the same intended use and the same or similar technological characteristics as the predicate device. The proposed spike is similar in design, having the same type of components such as a piercing component with protective cap, an air inlet and a distal luer lock adapter with cap as the predicate device. These components are also constructed of similar materials. Both devices are provided as sterile packaged devices sterilized by ethylene oxide for single use.

A table summarizing the comparison between the Universal Spike and the predicate device is provided below.

Characteristic	Predicate Device - K943181 Dispensing Pin with One-Way Valve	Proposed Universal Spike
Intended Use	Intended for the transfer of solutions from one container to another	For the transfer of solutions from one container to another
Components	Vented or non-vented spike with or without air filter and distal female luer lock hub (can be attached to syringe or IV fluid transfer set)	Vented spike with air inlet filter and distal female luer lock connector (can be attached to syringe or fluid transfer set)
Materials of construction	Spike Guard – LDPE	Spike Cap – LDPE
	Piercing Device – ABS	Spike Body – ABS
	Air Inlet Housing – Polypropylene Filter – Pallflex	Air Inlet Housing – Polypropylene Filter – 3 micron membrane
	Female Luer Lock – Polycarbonate	Female Luer Lock - ABS
	Female Luer Lock Cap – HDPE	Female Luer Lock cap – Polypropylene
	Back Check Valve Housing Top and Bottom – Polycarbonate Punched Disk – Silicone	N/A
Configurations	<ul style="list-style-type: none"> ▪ Normal sized spike or lower volume, mini spike ▪ Air-inlet vents or non-vented 	<ul style="list-style-type: none"> ▪ Normal sized spike ▪ Air inlet filter
Sterilization Method	Ethylene oxide	Ethylene oxide

*B. Braun Medical Inc.
510(k) Premarket Notification
Universal Spike*

Performance Testing

The proposed Universal Spike was subjected to functional and performance testing to demonstrate that the device performs as intended.

The following testing was performed on the subject device to the performance criteria listed or included in the referenced standard:

- Chemical Analysis (ISO 8536-4, ISO 10993-18)
- Visual Control (ISO 22413, ISO 8536)
- Fragmentation Test (ISO 22413)
- Penetration Force (ISO 8536-2)
- Spike retention / seal ability (ISO 8536-2)
- Patency Test (ISO 8536-4)
- Pressure Test / Leakage (no leakage shall be detected when device is subjected to air pressure of 450 mmHg)
- Pull Test (cap and spike must withstand a minimum tensile force of separation between 4.41- 44.13 Newtons)
- Free Flow (ISO 22413)
- Particulate Contamination (USP <788>)
- Luer testing (ISO 594-1)
- Biocompatibility (ISO 10993-1)
 - Cytotoxicity (MEM Elution, ISO 10993-5)
 - Delayed-type hypersensitivity (Guinea Pig Maximization, ISO 10993-10)
 - Intracutaneous Reactivity (ISO 10993-10)
 - Acute Systemic Toxicity (ISO 10993-11)
 - Hemocompatibility (Hemolysis, ASTM F756, ISO 10993-4)
 - Material-Mediated Pyrogenicity (Rabbit Pyrogen, USP <151>, ISO 10993-11)

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 device demonstrate that the Universal Spike is substantially equivalent to the predicate device.