December 9, 2020

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

Re: K201469
Trade/Device Name: Mini Spike Plus 6/8R
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: LHI
Dated: November 12, 2020
Received: November 13, 2020

Dear Angela Caravella:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 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,

CAPT Alan Stevens
Director (acting)
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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K201469

Device Name

Mini Spike Plus 6/8R

Indications for Use *(Describe)*

An IV additive dispensing pin for aspiration from single-dose containers with a 20 mm vial closure diameter and a 22mm vial body diameter (6R/8R).

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.

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510(k) Summary-K201469

1. Submitter Information

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Contact Person: Angela J. Caravella
Sr. Regulatory Affairs Specialist
Telephone Number: (610) 596 2966
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Email angela.caravella@bbraunusa.com
Date Prepared: 09 December 2020

2. Device Name and Classification

Device Trade Name: Mini Spike Plus 6/8 R
Common Name: Vial Adapter / IV Fluid Transfer Set
Classification Name: Intravascular Administration Set; 21 CFR 880.5440
Regulatory Class Class II (non-exempt)
Product Code: LHI

3. Predicate Device

Device Trade Name: Mini-Spike Plus
Common Name: Vial Adapter / IV Fluid Transfer Set
Classification Name: Intravascular Administration Set; 21 CFR 880.5440
510(k) Number: K983794

The predicate device 510(k) clearance for K983794 covers three models of the device Mini-Spike Plus. Substantial equivalence is demonstrated with the following two models which are covered by K983794:

- Mini-Spike Plus, #04550242
- Chemo Mini-Spike Plus, #412011

No reference devices were used in this submission.

4. Device Description

The Mini Spike Plus 6/8 R is an IV additive dispensing pin for aspiration from single-dose containers with the size 6R* or 8R*. It is intended for withdrawal and injection from/in vials.

The Mini Spike Plus 6/8 R transfer device is used for the preparation of medications contained in vials with a 20 mm vial closure diameter and a 22mm vial body diameter. The device is for single use and to only be used with single use drug dose vials.

The device is configured with a snap cap covering a luer lock female access, a grip plate which features an integrated air filter (0.45 µm) and a standard plastic piercing spike.

The device provides two separate internal channels:
- One for injection and withdrawal of fluids
- One for the pressure equalization between the vial and the environment

When the device's spike is pierced into a rubber stopper of a drug vial, these channels enable a fluid transfer between a syringe (that is connected with the device's luer connector on the top) and the vial.
The vial adapter enables a permanent connection between the Mini Spike Plus 6/8 R and the vial.

During the pressure equalization process there is an air exchange with the environment. In order to prevent any contamination of drugs being stored in the vials the air passes a 0.45µm bacteria retentive air filter.

* The container sizes 6R and 8R are related to the size definitions set out in ISO 8362-1 Injection Containers and accessories-Part 1: Injection vials made of glass tubing.

5. Indications for Use / Intended Use

Indications for Use:
An IV additive dispensing pin for aspiration from single-dose containers with a 20 mm vial closure diameter and a 22mm vial body diameter (6R/8R).

Intended Use:
Withdrawal and injection from/in vials.

6. Substantial Equivalence

Intended Use/Indications for Use - Discussion of differences
The intended use of the proposed and the predicate device are identical. The indications for use of the proposed and the predicate device are equivalent and do not create a new intended use:

- Both devices are intended for aspiration from and injection into vials.
- The proposed device indications for use are limited to vials with a 20 mm vial closure diameter and a 22mm vial body diameter (6R/8R).
- The indications for use of the proposed device fall within the intended use of the predicate device and, therefore, the two devices have the same intended use.*

The differences in wording of the intended use and indications for use between proposed device and predicate device do not affect safety and effectiveness and do not alter the intended use of the proposed device:

- The indications for use of the proposed device are a subset compared to the predicate device indications for use.
- Both devices are used by the same type of healthcare professionals under the same conditions of use.
- Both devices have an identical principle of operation as well as mechanism of action.
- The differences in wording in the indications for use statements do not introduce new questions regarding safety or effectiveness due to their similarities in purpose, function and conditions of use.

*Refer to Section IV.D.1. of the Guidance "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]", issued July 28, 2014.

Technological Characteristics - Discussion of differences
The technological characteristics of the proposed device are substantially equivalent to the predicate device in regards to the technological characteristics as compared in Section 7 below.

Conclusion on Substantial Equivalence
The proposed device Mini Spike Plus 6/8 R has the same intended use and equivalent indications for use as the predicate device. The proposed device has similar technological characteristics to the predicate, and the descriptive and performance information provided within this premarket notification demonstrates that:

- any differences do not raise different questions of safety and effectiveness that the predicate device; and
- the proposed device is at least as safe and effective as the legally marketed predicate device.

Based on the comparison of the intended use and the technological characteristics the proposed Mini Spike Plus 6/8 R is substantially equivalent to the currently marketed predicate Mini-Spike Plus.

7. Comparison with Technological Characteristics with the Predicate Device

The technological characteristics of the proposed Mini Spike Plus 6/8 R are substantially equivalent to the predicate Mini-Spike Plus in regards to the following technological characteristics:

- Principle of operation, mechanism of action and conditions of use are identical between proposed device and predicate device.
- Material Composition is equivalent. Material composition of proposed device does not raise new questions of safety and effectiveness, as demonstrated by performance testing and biocompatibility evaluation.
- Physical Specifications are identical, except the proposed devices new component Vial Adapter. The Vial Adapter does not raise new questions on safety and effectiveness, as demonstrated by performance testing.
- Design Features & Interfaces are identical, except the proposed devices new component Vial Adapter. Additional performance verification of the proposed device with Vial Adapter does not raise new questions on safety and effectiveness.
- Sterilization method, SAL Level and sterilization cycle are equivalent between proposed device and predicate device. Differences do not raise new questions on safety and effectiveness.
- Packaging configuration and labeling are equivalent. Differences do not raise new questions on safety and effectiveness.

Intended Use / Indications for Use Comparison			
Characteristic	**Proposed Device:** Mini Spike Plus 6/8 R **#4550315-02**	**Predicate Device:** K983794; Mini-Spike Plus Models: Mini-Spike Plus, #04550242 (Model 1) Chemo Mini-Spike Plus, #412011 (Model 2)	**Comparison**
Product Code and Regulation	LHI 21 CFR 880.5440	LHI 21 CFR 880.5440	Identical
Classification	Class II (non-exempt)	Class II (non-exempt)	Identical
Review Panel	General Hospital	General Hospital	Identical
Type of Use	Prescription use only	Prescription use only	Identical
Conditions of Use	Single Use	Single Use	Identical
Sterility	Sterile using Ethylene Oxide	Sterile using Gamma Radiation	Equivalent
Shelf Life	5 years	5 years	Identical
Indications for Use	An IV additive dispensing pin for aspiration from single-dose containers with the size 6R or 8R.	An IV additive dispensing pin for aspiration from multi-dose containers or injection into IV Systems (IV Bags)	Equivalent
Intended Use	Withdrawal and injection from/in vials.	Withdrawal and injection from/in multidose vials.	Identical Limitations of indicates for use for proposed device fall

			within the intended use of the predicate device, therefore the two devices have the same intended use.
Technological Characteristic Comparison			
General Characteristics			
Principle of Operation / Mechanism of Action	The device provides two separate channels: - One for injection and withdrawal of fluids - One for the pressure equalization between the vial and the environment When the device's spike is pierced into a rubber stopper of a drug vial, these channels enable a fluid transfer between a syringe (that is connected with the device's luer connector on the top) and the vial.	The device provides two separate channels: - One for injection and withdrawal of fluids - One for the pressure equalization between the vial and the environment When the device's spike is pierced into a rubber stopper of a drug vial, these channels enable a fluid transfer between a syringe (that is connected with the device's luer connector on the top) and the vial.	Identical
Conditions of Use	Single Use	Single Use	Identical
Material Composition			
Grip Piece	**Material:** SAN/ABS (Styrene-Acrylonitrile / Acrylonitrile-Butadiene-Styrene)	**Material:** SAN/ABS (Styrene-Acrylonitrile / Acrylonitrile-Butadiene-Styrene)	Identical
Piercing Spike	**Material:** SAN/ABS (Styrene-Acrylonitrile / Acrylonitrile-Butadiene-Styrene)	**Material:** SAN/ABS (Styrene-Acrylonitrile / Acrylonitrile-Butadiene-Styrene)	Identical
Snap Cap	**Material**: PP (Polypropylene)	**Material**: PP (Polypropylene)	Identical
Air Filter	**Material:** AVC on PA 6 (Acrylonitrile-Vinylchloride Copolymer on Polyamide)	**Material:** AVC on PA 6 (Acrylonitrile-Vinylchloride Copolymer on Polyamide)	Identical
Protective Cap	N/A for proposed device.	**Material:** PE-LD (Low-Density Polyethylene)	N/A for proposed device.
Vial Adapter	**Material:** Polystyrene	N/A	New component. As demonstrated by performance testing vial adapter does not raise new questions on safety and effectiveness.
Piercing Spike Lubricant	**Material:** Silicone Oil	**Material:** Silicone Oil	Identical
Physical Specifications			
Dimensions	Mini Spike (entire device without Vial Adapter): Height: 54.7 mm Length: 34 mm Width: 30 mm	Mini Spike (entire device without Protective Cap): Height: 54.7 mm Length: 34 mm Width: 30 mm	Identical for Mini Spike and Piercing Spike Vial adapter dimensions do not raise questions on

	Piercing Spike: Length: 21 ± 0.2 mm Diameter: 3.98 +0.2/-0.3 mm Vial Adapter: Height: 64 mm Length: 38 mm Width: 30 mm	Piercing Spike: Length: 21 ± 0.2 mm Diameter: 3.98 +0.2/-0.3 mm	safety and effectiveness.
Connector Type	Luer Lock	Luer Lock	Identical
Color	Snap Cap: Green Grip Piece & Piercing Spike: White Vial Adapter: Transparent	Snap Cap: Green (Model 1) Grip Piece & Piercing Spike: White Protective Cap: Green	Identical (Snap Cap; Grip Piece & Piercing Spike) Transparent vial adapter does not raise questions on safety and effectiveness.
Vial Adapter	Vial adapter keeps proposed device connected to a vial with the size 6R or 8R.	N/A	New component. As demonstrated by performance testing vial adapter does not raise new questions on safety and effectiveness.
Design Features & Interfaces			
Luer Connector Cover	Snap Cap	Snap Cap	Identical
Device User Interface	Grip Piece	Grip Piece	Identical
Interface to Syringe	Luer Lock Connector	Luer Lock Connector	Identical
Interface to Vial	Piercing spike with dimensions: Length: 21 ± 0.2 mm Diameter: 3.98 +0.2/-0.3 mm	Piercing spike with dimensions: Length: 21 ± 0.2 mm Diameter: 3.98 +0.2/-0.3 mm	Identical
Air Filter	0.45µm	0.45µm (Model 1)	Identical
Protective Cap	N/A for proposed device	Pull Off Cap that prevents piercing of sterile barrier system during transport; needs to be removed prior to product usage	Functionally Equivalent
Vial Adapter	Vial adapter keeps proposed device connected to vial.	N/A	New component. Vial adapter keeps proposed device connected to vial. As demonstrated by performance testing vial adapter does not raise new questions on safety and effectiveness
Sterilization			
Sterilization Method	Ethylene Oxide	Gamma Radiation	Equivalent As demonstrated by

			sterilization validation the sterilization method does not raise new questions on safety and effectiveness
Sterility Assurance Level (SAL)	10^{-6}	10^{-6}	Identical
Sterilization Cycle	90% EO / 10% CO_2	Isotope: Cobalt 60 Minimum Dose 18.0 KGy Maximum Dose: 30.0 KGy	Equivalent As demonstrated by sterilization validation the sterilization method does not raise new questions on safety and effectiveness
Packaging			
Packaging – Sterile Barrier System	Thermoformed film sealed with printed medical grade paper	Thermoformed film sealed with printed medical grade paper	Equivalent As demonstrated by packaging validation the packaging does not raise new questions on safety and effectiveness

8. Performance Testing

Performance Testing Bench

Functional performance bench testing was conducted to demonstrate that the Mini Spike Plus 6/8R device performs as intended. No clinical testing was performed as this device does not require clinical studies to demonstrate substantial equivalence with the predicate device.

The following performance tests were conducted in support of the substantial equivalence determination:

Standard	**Test Performed**
ISO 22413:2010	• Particle Contamination • Fragmentation • Air Tightness • Free Flow • Penetration Force • Tensile Load • Visual Inspection • Chemical Analysis
ISO 80369-7:2016	• Luer Connector Leakage, Stress Cracking & Resistance Testing • Dimensional Accuracy
ISO 11607-1: 2006/Amd1:2014 ASTM F 1980-16 ASTM F1886/F1886M-16 ASTM D4169-16 ASTM D4332-14 ASTM F88/F88M-15 ASTM F1929-15 ASTM F2096-11 ASTM F2252/F2252M-13 DIN 58953-6:2016 ISO 11607-2: 2006/Amd:2014	• Sterile Barrier System Validation
USP <85>, USP <161>	• Bacterial Endotoxin (LAL Gel Clot Test)
Internal device performance test methods	• Fluid burst pressure of air filter membrane • Dynamic tensile load between Mini Spike and Vial Adapter
USP <788>	• Particulate Contamination

Biocompatibility Testing

The final finished Mini Spike Plus 6/8R was evaluated according to ISO 10993-1:2009.
The following biocompatibility testing was performed with the reference standard utilized:

Standard	Test Performed
ISO 10993-5:2009	• Cytotoxicity
ISO 10993-10:2010	• Sensitization • Intracutaneous Reactivity / Irritation
ISO 10993-11:2006	• Acute Systemic Toxicity
ISO 10993-4:2002/Amd1 ASTM F756 (2013)	• Hemolysis
ISO 10993-11:2006 USP 38 <151>	• Material Mediated Pyrogenicity

9. Conclusion

The proposed Mini Spike Plus 6/8R has met all established acceptance criteria for performance testing and design verification testing. Results of functional performance and biocompatibility testing conducted with the Mini Spike Plus 6/8R device demonstrate that the proposed device supports a substantial equivalence determination to the predicate device as described in Section 6.