July 30, 2020

MPS Medical, Inc.
Paul Gasser
Medical Device RA/QA Consultant
830 Challenger Street, Suite 200
Brea, CA 92821

Re: K200082
Trade/Device Name: BD Univia RightFit Enteral Extension Sets and Transitional Adapters
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: PIF, PIO
Dated: June 30, 2020
Received: July 1, 2020

Dear Paul Gasser:

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,

for
Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200082

Device Name
BD UniVia™ RightFit Extension Sets and Transitional Adapters

Indications for Use *(Describe)*
BD UniVia™ RightFit enteral extension set is indicated for use in neonatal, pediatric and adult patients in connection with nasogastric/orogastric enteral feeding tube to provide nutrition via nasal or oral gastric tube placements.

BD UniVia™ RightFit transition adapter allows connection of BD UniVia™ RightFit Extension Sets to non-BD UniVia™ RightFit enteral systems.

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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Traditional 510(k) Summary

Submitter:	MPS Medical, Inc. 830 Challenger, Suite 200 Brea, CA 92821 USA
Contact:	Susan Ginsberg Director, R&D MPS Medical, Inc. Telephone: 844-641-3814 E-mail: sginsberg@mpsmedical-inc.com
Date Summary Prepared:	January 15, 2020
Device Trade Name:	BD UniVia™ RightFit Extension Sets and Transitional Adaptors
Common Name:	Enteral Extension Sets
Classification Name:	Gastrointestinal tube and accessories (21 CFR 876.5980)
Regulatory Class:	Class II
Product Code:	PIF, PIO
Predicate Device:	VR Medical Feeding Tube (510(k) K180236)
Reference Device:	Neomed Enteral Extension Set (510(k) K100288)

Device Description:
Enteral Extension Sets are intended to provide access from a feeding tube to a syringe or nutritional source accepting a connector for enteral applications. They are available in two configurations:

- Standard enteral extension sets, with a variation in tube length and diameter
- Bifurcated extension sets, which allow for medication or additional delivery without disrupting the feeding line with a variation in tube length

Enteral Extension Sets consists of flexible tubing with a purple strip on the tubing. The enteral connectors are purple in color for ease of identification of enteral feeding lines.

The female connector has a tethered cap to cover the connector when not used to prevent fluid leakage. A clamp is present over the tube to stop the fluid flow as needed.
Transitional Adapters allow for the connection of RightFit Enteral Extension Sets to non-enteral systems. The Transitional Adapters are available in two configurations:

- Enteral female to enteral female
- Enteral male to enteral male

Indications for Use:
BD UniVia™ RightFit enteral extension set is indicated for use in neonatal, pediatric and adult patients in connection with nasogastric/orogastric enteral feeding tube to provide nutrition via nasal or oral gastric tube placements.

BD UniVia™ RightFit transition adapter allows connection of BD UniVia™ RightFit Extension Sets to non-BD UniVia™ RightFit enteral systems.

Statement of Equivalence:
The subject device and the predicate share a similar intended use and have similar technological characteristics.

Key differences between the subject and predicate devices are reflected in the following table.

Characteristic	Predicate Device VR Medical Enteral Feeding Extension Set (EFES)	Subject Device MPS Medical Enteral Extension Set and Transitional Adapters
Enteral Extension Sets		
Length (inches)	22 - 60	8 - 60
ID/OD (mm)	Unknown	0.89/2.4, 2.1/3.5, 3.0/4.1
Connectors	Male/female per ISO 80369-3	Same
Transitional Adapters		
Length (inches)	None	1.9 - 2.2
ID/OD (mm)	None	2.1/3.5
Connectors	None	Male and female connectors per ISO 80369-3

The BD UniVia™ RightFit enteral extension sets and transitional adapters are substantially equivalent to the predicate device.

Summary of Non-Clinical Performance Data:
Device evaluation consisted of *in vitro* testing performed pursuant to MPS Medical's risk analysis. All data met the acceptance criteria and fell within pre-determined product specifications and external standard requirements. The following testing was performed to support the determination of substantial equivalence:

Visual
Insertion and removal force
Dimensions
Leakage
Stress cracking
Resistance to separation
Resistance to overriding
Disconnection by unscrewing
Kink resistance
Tensile force
Flow rate
Human factors

Biocompatibility Testing:
Biocompatibility testing was conducted in accordance with ISO 10993-1.

Sterilization Testing:
Sterilization testing was conducted in accordance with ISO 11135 to ensure a sterility assurance level (SAL) of 10^{-6}.

Transportation and Shelf Life Testing:
Shipping and distribution testing was conducted in accordance with ISO 11607-1.

Shelf life testing was performed.

The data from the *in vitro* testing above supports the substantial equivalence of the subject device to the predicate device.

Summary of Pre-Clinical and Clinical Data:
No pre-clinical or clinical data were generated to establish substantial equivalence. Bench data are considered adequate to support a determination of substantial equivalence.

Summary:
Based on the intended use and *in vitro* performance information provided in this premarket notification, the BD UniVia™ RightFit Extension Sets and Transitional Adaptors are substantially equivalent to the predicate device.