April 12, 2023

Poly Medicure Limited
% Roger Gray
VP Quality and Regulatory
Donawa Lifescience Consluting Srl
Piazza Albania 10
Rome, 00153
Italy

Re: K220312
Trade/Device Name: Polyfusion IV Administration Sets
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FPA
Dated: March 13, 2023
Received: March 14, 2023

Dear Roger Gray:

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,

David Wolloscheck, Ph.D.
Acting Assistant Director
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)*

K220312

Device Name

Polyfusion IV Administration Sets

Indications for Use *(Describe)*

For administration of fluid from a container into the patient vascular system through a vascular access device.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K220312 510(k) Summary

Device Name:	Polyfusion IV Administration Sets
Type of 510(k) submission:	Traditional
Preparation Date:	April 12, 2023
Manufacturer:	Poly Medicure Ltd PA 010-018, 010-019, Mahindra World City (Jaipur) Ltd, Multi Product SEZ, Jaipur Rajasthan-302237 India
Phone:	+91-129-3355070
FDA Establishment Reg. Number:	9616991
Owner/Operator Reg. Number:	9044462
510(k) Owner and Submitter:	Poly Medicure Ltd PA 010-018, 010-019, Mahindra World City (Jaipur) Ltd, Multi Product SEZ, Jaipur Rajasthan-302237 India
510(k) Contact:	Mr Roger Gray VP Quality and Regulatory Donawa Lifescience Consulting Piazza Albania 10 00153 Rome Italy
Phone: **Fax:** **Email:**	+39 06 578 2665 +39 06 574 3786 rgray@donawa.com
FDA Product Code:	FPA
FDA Regulation Number:	21 CFR 880.5440
FDA Classification Name:	Intravascular administration set
Classification Panel:	General Hospital
Common Name:	Intravascular Administration Set
FDA Classification:	Class II
Submission Type:	510(k)
Indications for Use:	For administration of fluid from a container into the patient vascular system through a vascular access device.

Device Description:
The Polyfusion IV Administration Sets are available in multiple configurations. In more detail:

Polyfusion NFV IV Administration Sets: Used to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into the vein. The set may include a vented or non-vented universal spike, drip chamber, fluid delivery tubing, flow regulator, stop cock, back check valve, needle free valves, 0.2 µm inline filter, slide clamp, Luer connectors, and priming filters. Four different drip rates are available, viz: 10 drops/ml, 15 drops/ml, 20 drops/ml and 60 drops/ml. Different lengths are available, from 196 cm to 276 cm, together with options for certain components being made either from PVC which has not been manufactured using DEHP plasticiser or using an alternative material which has not been manufactured with either PVC or DEHP. The sets are labeled for prescription use (Rx only) and are supplied sterile for single use only, with a sterilization assurance level (SAL) of 10^{-6} achieved by means of a validated ethylene oxide sterilization process.

Polyfusion Air Stop IV Administration Sets: Used to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into the vein. The inclusion of an air stop filter maintains a constant fluid level in fluid delivery tubing and reduces the possibility of air entering the line when the I.V. bottle/bag is empty. The set may include a vented or non-vented universal spike, drip chamber, air stop filter, fluid delivery tubing, flow regulator, stop cock, back check valve, needle free valves, 0.2 µm inline filter, slide clamps, Luer connectors, and priming filters. Four different drip rates are available, viz: 10 drops/ml, 15 drops/ml, 20 drops/ml and 60 drops/ml. Different lengths are available from 196 cm to 276 cm, together with options for certain components being made either from PVC which has not been manufactured using DEHP plasticiser or using an alternative material which has not been manufactured with either PVC or DEHP. The sets are labeled for prescription use (Rx only) and are supplied sterile for single use only, with a sterilization assurance level (SAL) of 10^{-6} achieved by means of a validated ethylene oxide sterilization process.

Performance data:
Non-clinical testing of the Polyfusion IV Administration Sets has included successful compliance testing with the following standards, most of which are FDA-recognized:

- ISO 8536-4:2019, FDA recognition # 6-447
- ISO 8536-14:2016, not FDA recognized
- ISO 80369-7:2021, FDA recognition # 5-97
- USP <788> Method 1, not FDA recognized
- ISTA-3A:2018, FDA recognition # 5-126
- ASTM F-1886 / F-1886-M-16, FDA recognition # 14-501
- ASTM F-2096, FDA recognition # 14-359
- ASTM F-1929, FDA recognition # 14-484
- EN 868-5:2018, not FDA recognized
- Microbial Ingress testing

Biocompatibility:
Biocompatibility of components in direct or indirect contact with the patient has been established by testing in accordance with the matrix included in Annex A of ISO 10993-1:2018, while taking into consideration relevant FDA guidance, including:

- Cytotoxicity (ISO 10993-5:2009, FDA recognition # 2-245)
- Sensitization (ISO 10993-10:2010, FDA recognition # 2-174)
- Irritation or intracutaneous reactivity (ISO 10993-10:2010, FDA recognition # 2-174)
- Acute systemic toxicity (ISO 10993-11:2017, FDA recognition # 2-255)
- Subacute/subchronic toxicity (ISO 10993-11:2017, FDA recognition # 2-255)
- Material mediated pyrogenicity (ISO 10993-11:2017, FDA recognition # 2-255)
- Hemocompatibility (ISO 10993-4:2017, FDA recognition # 2-248)

Sterilization and shelf life:
Sterilization of the Polyfusion admin sets is achieved by use of a validated ethylene oxide gas cycle, achieving a sterilization assurance level (SAL) of 10-6. Ethylene oxide residuals are within specified limits

A shelf life of 5 years has been established by testing the integrity of the sterile packaging following accelerated aging (per ASTM F 1980-16) in accordance with the following standards:

- ISO 8536-4:2019, FDA recognition # 6-447
- ISO 8536-14:2016, not FDA recognized
- ISO 80369-20:2015, FDA recognition # 5-97
- USP <788> 2012, not FDA recognized
- ASTM F-1929, FDA recognition # 14-484
- ASTM F-2096, FDA recognition # 14-359
- ASTM F-88 / F88M-15, FDA recognition # 14-482
- USP <85> 2012, FDA recognition # 14-561

Human factors:
A human factors study has also been carried out in accordance with ISO 23908:2011, while taking into consideration relevant FDA guidance.

Substantial equivalence:
The predicate device selected for comparison with the Polyfusion IV administration Admin Sets is:

Predicate Device: .....Intravascular Administration Set
Sponsor: .....Baxter Healthcare Corp.
510(k) Number: K203609
Clearance Date: .....30 September 2021
FDA Product Code: .....FPA
Classification Name: .....Intravascular Administration Set
Regulation No: .....21 CFR 880.5440
Class: II

Predicate device comparison table:
The following Table 1 provides evidence of substantial equivalence of the subject device with the selected predicate device.

Table 1: Predicate device comparison table			
Feature	**Subject device**	**Predicate device**	**Similarity**
Device name	Polyfusion IV Administration Sets	Intravascular Administration Sets	N/A
Device Manufacturer	Poly Medicure, India	Baxter Healthcare Corporation	N/A
510(k) Reference	This submission	K203609	N/A
FDA Product Code	FPA	FPA	Same
FDA Classification Name	Intravascular Administration Set	Intravascular Administration Set	Same
FDA Regulation Number	21 CFR 880.5440	21 CFR 880.5440	Same

Table 1: Predicate device comparison table			
Feature	**Subject device**	**Predicate device**	**Similarity**
Device description:	Available in multiple configurations that may include different materials in contact with delivered fluid, different lengths and drip rates and different valves and secondary access ports	Available in multiple configurations that may include different materials in contact with delivered fluid, different lengths and drip rates and different valves and secondary access ports	Same
Gravity feed only?	Yes	No, maybe used with infusion pump	Different Comment #1
Indications for use	For administration of fluid from a container into the patient vascular system through a vascular access device.	For the administration of fluids from a container into the patient's vascular system through a vascular access device.	Same
Material in contact with delivered fluid	Either PVC not made with DEHP, or material not made with either PVC or DEHP (TPE and TPO)	Either PVC made with DEHP, or PVC not made with DEHP	Different Comment #2
Vented/non-vented spike	Option for both	Option for both	Same
Lengths	196 to 276 cm	175.26 to 339.09 cm	Different Comment #3
Drip rates	10 to 60 drips per minute	10 drips per minute	Different Comment #4
Priming volume	Approx 25 ml	6.1 to 21.2 ml	Different Comment #5
Single use	Yes	Yes	Same
Sterile	Yes, SAL 10^{-6}	Yes, SAL 10^{-6}	Same
Sterilization method	Ethylene oxide	Radiation	Different Comment #6
Shelf life	5 years	2 years	Different Comment #7
Biocompatibility	Biocompatible in accordance with ISO 10993 series and FDA guidance	Biocompatible in accordance with ISO 10993 series and FDA guidance	Same
Performance standards	ISO 8536-4:2019 ISO 8536-14:2016 ISO 80369-20:2015 USP <788> Method B Microbial ingress	ISO 594-1 ISO 594-2 ISO 80369-7:2016 USP <788> Method 1 Microbial ingress	Similar
Prescription use?	Rx only	Rx only	Same

Substantial Equivalence discussion

The subject device and the predicate device have many identical, similar or substantially equivalent properties or features. The differences that exist and are identified in the above table are explained in the following paragraphs.

Comment #1: Gravity feed

The subject device is indicated for gravity feed use only, whereas the predicate device is indicated for both gravity feed and feed via an infusion pump. While the predicate device offers an alternative to gravity feed use, when used for gravity feed, the two devices have very similar characteristics and specifications, with no new or different questions of safety or effectiveness being raised that would affect the substantial equivalence of the two devices.

Comment #2: Material in contact with delivered fluid
While both the subject device range and the predicate device range include sets in which the material in contact with delivered fluid is 'DEHP-free PVC', there is a material difference between the other sets in the two ranges. In this respect, the predicate device range includes material which is PVC manufactured with DEHP, while the subject device range includes non-PVC materials which do not include DEHP. These materials are a thermoplastic elastomer (TPE) and a thermoplastic polyolefin (TPO). This difference has been shown by the results of bench tests carried out in accordance with international, FDA-recognized, standards, to not raise any new or different questions of safety or effectiveness that would affect the substantial equivalence of the two device ranges.

Comment #3: Available lengths
The predicate device range includes admin sets that have shorter shortest lengths and longer longest lengths than the subject device range, but these differences are not significant in terms of safety and effectiveness, with the set lengths being substantially equivalent.

Comment #4: Drip rates
The subject device range includes a variety of drip rates, whereas the predicate device range has only one stated drip rate, which is equivalent to the lowest drip rate available within the subject device range. While the subject device offers alternative drip rates, when used at 10 drips/min, the two devices have very similar characteristics and specifications, with no new or different questions of safety or effectiveness being raised that would affect the substantial equivalence of the two devices.

Comment #5: Priming volume
There is a difference in priming volume between the subject device range and predicate device range, with the subject device range having a single stated priming volume for all variants, while the predicate device range includes different priming volumes for different variants. No new or different questions of safety or effectiveness are raised by this difference that would affect the substantial equivalence of the two device ranges.

Comment #6: Sterilization
The subject device is sterilized by means of ethylene oxide, whereas the predicate device is sterilized by means of radiation. Both sterilization methods result in a validated Sterility Assurance Level (SAL) of 10-6, so the devices are substantially equivalent in this respect with no new or different questions of safety or effectiveness being raised.

Comment #7: Shelf life
The subject device has a validated shelf life of five years, compared with the two year shelf life validated for the predicate device. This difference in shelf life raises no new or different questions of safety or effectiveness that would affect the substantial equivalence of the two devices.

Performance standards
The subject device has been tested in accordance with newer international standards than the predicate device, but the purposes and scope of the standards used for both subject and predicate devices are the same or similar, with no new or different questions of safety or effectiveness being raised that would affect the substantial equivalence of the two devices.

Conclusion
The subject and predicate devices have very similar indications for use and fundamental technological characteristics. Any differences in technological characteristics between subject and predicate devices are addressed by means of specific features present in the reference devices. These differences do not raise different questions of safety and effectiveness. The performance data demonstrate that the subject device is substantially equivalent to the predicate device.