September 18, 2020

Smiths Medical ASD, Inc.
% Danielle Besal
Principal Consultant
MRC Global, LLC
9085 East Mineral Circle, Suite 110
Centennial, CO 80112

Re: K192375
Trade/Device Name: Intellifuse™ Administration and Intellifuse™ Blood Administration Sets
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FPA
Dated: September 9, 2020
Received: September 11, 2020

Dear Danielle Besal:

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 Payal Patel
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)*
K192375

Device Name
Intellifuse™ Administration Sets and Intellifuse™ Blood Administration Sets

Indications for Use *(Describe)*
Intellifuse™ Administration Sets are indicated for the delivery of fluids from a container to a patient's vascular system.

Intellifuse™ Blood Administration Sets are indicated for the delivery of fluids including but not limited to blood and blood products from a container to a patient's vascular system.

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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510(k) Summary
K192375

Date:	September 18, 2020
Sponsor:	Smiths Medical 6000 Nathan Lane North, Minneapolis, MN 55442, USA Phone: 763.383.3000
Establishment Registration:	3012307300
Primary Contact:	Danielle Besal Principal Consultant | MRC Global Phone: 901.827.8670
Proprietary Name:	Intellifuse™ Administration Sets and Intellifuse™ Blood Administration Sets
Regulation Name:	Intravascular administration set
Regulation:	21 CFR 880.5440
Product Codes:	FPA
Device Class:	II
Panel:	General Hospital
Predicate Device:	Hospira Administration Sets: Hospira Primary Sets, Hospira Extension Sets, Hospira Burette Sets, and Hospira Blood Sets (K160870, 21 CFR 880.5440, FPA)

Device Description:
Intellifuse™ Administration Sets and Intellifuse™ Blood Administration Sets are single use, disposable, sterile fluid path, intravenous administration sets used to deliver fluids, medications, blood and blood products from a container into a patient's vascular system depending on the configuration selected. These sets are available in multiple configurations and may be comprised of various components which are broadly used throughout industry tubing, spike assemblies, drip chambers, check valves, clamps, needleless access connector, injection sites, in-line filters, luer connectors, and a tube frame assembly. The administration sets are intended to administer fluids with gravity flow. The IV Administration sets are configured to ensure the intended use of the device is met. The devices are intended for the general patient population.

Indications for Use:
Intellifuse™ Administration Sets are indicated for the delivery of fluids from a container to a patient's vascular system.

Intellifuse™ Blood Administration Sets are indicated for the delivery of fluids including but not limited to blood and blood products from a container to a patient's vascular system.

Substantial Equivalence:
The technology for Intellifuse™ Administration Sets and Intellifuse™ Blood Administration Sets is similar between the subject and the predicate devices as described in the table below.

	Subject: Intellifuse™ Administration Sets & Intellifuse Blood Administration Sets (K192375)	**Predicate: Hospira Administration Sets (K160870)**	**Substantial Equivalence Discussion**
Manufacturer	Smiths Medical	Hospira	N/A
Indications for Use	Intellifuse™ Administration Sets are indicated for the delivery of fluids from a container to a patient's vascular system. Intellifuse™ Blood Administration Sets are indicated for the delivery of fluids including but not limited to blood and blood products from a container to a patient's vascular system.	Hospira Primary sets are indicated for the delivery of fluids from a container to a patient's vascular system. Hospira Extension sets are indicated for the delivery of fluids from a container to a patient's vascular system. Hospira Burette sets are indicated for the delivery of fluids from a container to a patient's vascular system. Hospira Blood sets are indicated for the delivery of fluids including but not limited to blood and blood products from a container to a patient's vascular system	The subject Intellifuse™ Administration Sets encompass various configurations (including primary, secondary, and burette sets) that differ slightly from the predicate set configurations, but all are equivalently intended for the delivery of fluids from a container to a patient's vascular system. The subject blood sets have the same indications as the blood sets for the predicate device. Substantially equivalent.
Usage	Single Patient Use, Disposable	Single Patient Use, Disposable	Identical; substantially equivalent
Available Design Features	PVC tubing, low light absorption tubing, bag spike and cap drip chamber, bag spike handle, drip chamber, burette subassembly, check valve, pinch clamp, roller clamp, injection site assembly, needleless access connector (nSyte™), filter, male luer adapter with cap, blood chamber Gravity Flow	Male and female luer adapter with cap, piercing pin connector, tubing, flow control device, filter, in-line adapter, injection site assembly, luer activated needleless valve connector (Nuitiv™ Connector), check valve, burette chamber, blood chamber Gravity Flow	Equivalent common components are used in all sets and performance testing shows compliance with ISO requirements and acceptability for device's intended use. Substantially equivalent
Priming Volume	Primary Sets: 24-29 mL Blood Sets: 29-30 mL Secondary Set: 14 mL	Not disclosed	Priming testing supports acceptability of device for its intended use. Substantially equivalent.
Drops / mL	Burette Sets: 60 drops/mL All other sets: 20 drops/mL	Not disclosed	Performance testing supports acceptability of device for its intended use. Substantially equivalent.

	Subject: Intellifuse™ Administration Sets & Intellifuse Blood Administration Sets (K192375)	Predicate: Hospira Administration Sets (K160870)	Substantial Equivalence Discussion
Materials	ABS, DEHT, PVC HDPE, Acrylic & Nylon LDPE, MABS, PC, Silicone, Flurosilicone, Clear ABS, LDPE, Polyisoprene, Acrylic, E-PTFE, Polyurethane (biocompatible, non-DEHP, not manufactured with natural rubber latex)	Polycarbonate, copolyester, silicone, acrylic, polypropylene, non-phthalate PVC, HDPE, ABS, nylon	Similar, all differences supported by ISO 10993 biocompatibility testing. Substantially Equivalent
Sterility	Sterile fluid path, EO SAL 10^{-6}	Sterile, method not disclosed, SAL 10^{-6}	Predicate sterilization method not disclosed; however, both devices are validated to the same sterility assurance level and the subject sterilization has been validated and is acceptable for its intended use; substantially equivalent.

The differences between the subject and predicate devices are minimal and include differences in the material construction of the various subcomponents. The predicate device also comprises extension sets, which are not part of this submission. Smiths Medical has determined materials differences do not affect the device's intended use, indication for use, or alter the device's fundamental scientific technology for fluid, blood, or blood product administration. In addition, the performance requirements were met by the tests performed on the device.

Non-Clinical Performance Data:
Non-clinical testing of the components comprised in each configuration of the subject devices were assessed and tested appropriately to design controls; i.e., design verification, design validations. The test results conclude that the Intellifuse™ Administration Sets and Intellifuse™ Blood Administration Sets to be substantially equivalent to the predicate device. Testing listed below passed and results were verified against requirements:

- ISO 8536-4, "Infusion equipment for medical use – Part 4: Infusion sets for single use, gravity feed"
- ISO 1135-4, " Transfusion equipment for medical use – part 4 Transfusion sets for single use, gravity feed"
- ISO 594-1, "Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 1: General Requirements"
- ISO 594-2, "Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 2: Lock fittings"
- Particulate assessment (USP <788>)
- Microbial Ingress (Internal test method)
- Pinch Clamp (Internal test method)
- Check Valve (ISO 8536-12)
- Needleless Access Connector (Internal test method)
    - Hydrostatic pressure
    - Translucency
    - Inspection
- Burette Chamber (ISO 8536-5)

- Biocompatibility (ISO 10993-1)
    - In addition, biocompatibility of needleless connector for K163172 was leveraged for needleless access connector
    - Pyrogenicity (material mediated/bacterial endotoxins)
- Sterilization – SAL 10^{-6}
    - ISO 11135, "Sterilization of health care Products – Ethylene Oxide – Requirements for development, validation and routine control of a sterilization process for medical devices
- Packaging (transport and distribution)
    - ISO 11607-1, "Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems

Clinical Performance Data:
Clinical testing was not necessary for the determination of substantial equivalence.

Conclusion:
Smiths Medical concludes the differences between the subject and predicate device do not impact the indications for use, intended use, and do not raise new questions of safety or effectiveness imposed on the patient or device use; therefore, the subject device, for Intellifuse™ Administration Sets and Intellifuse™ Blood Administration Sets, is considered substantially equivalent to the predicate.