November 9, 2017

INTERVENE Group Limited
Homer Trieu
Regulatory Affairs Manager
Russell Building, Brunel Science Park
Kington Lane, Uxbridge
Middlesex UB8 3PQ
UNITED KINGDOM

Re: K170900
Trade/Device Name: DASH 6® NRFit: Lock Syringe, Slip Syringe, Plastic LOR Device, Introducer Needle, Syringe Caps, Drawing Up Filter Straw, Blunt Drawing Up Needle (with and without filter), Bacterial Disc Filter, Epidural Flat Filter, Tuohy Borst Adapter, Syringe-Syringe adapter, Needle Hub Cap, Epidural Catheter Feeder
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF, BSN, BSO, BSP
Dated: October 6, 2017
Received: October 10, 2017

Dear Homer Trieu:

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.

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170900

Device Name
DASH 6® NRFit: Lock Syringe, Slip Syringe, Plastic LOR Device, Introducer Needle, Syringe Caps, Drawing Up Filter Straw, Blunt Drawing Up Needle (with and without filter), Bacterial Disc Filter, Epidural Flat Filter, Tuohy Borst Adapter, Syringe-Syringe adapter, Needle Hub Cap, Epidural Catheter Feeder.

Indications for Use *(Describe)*
The DASH 6® NRFit Lock syringe and DASH® NRFit Slip Syringe are intended to be used with ISO 80369-6 NRFit neuraxial compliant devices for administration of neuraxial medication.

The DASH 6® NRFit Plastic LOR Device is intended to be used with ISO 80369-6 NRFit neuraxial compliant epidural needle for locating the epidural space.

Accessories:
DASH 6® Introducer Needle is intended to be used with ISO 80369-6 NRFit neuraxial compliant spinal needle for guiding the placement of the spinal needle into the arachnoid/epidural space.

DASH 6® NRFit Syringe Cap is intended to be used with ISO 80369-6 NRFit neuraxial syringes for sealing the tip of the syringe.

DASH 6® NRFit Drawing Up Filter Straw are intended to be used with ISO 80369-6 NRFit neuraxial syringe for the drawing up of neuraxial medication and anesthetic.

DASH 6® NRFit Blunt Drawing Up Needle (with and without filter) is intended to be used with ISO 80369-6 NRFit neuraxial syringe for the drawing up of neuraxial medication and anesthetic.

DASH 6® NRFit Bacterial Disc Filter is intended to be used with ISO 80369-6 NRFit neuraxial compliant devices to ensure aseptic administration of neuraxial medication and anesthetic.

DASH 6® NRFit Epidural Flat Filter is intended to be used with ISO 80369-6 NRFit neuraxial compliant devices to ensure aseptic administration of neuraxial medication and anesthetic.

DASH 6® NRFit Tuohy-Borst Adapter is intended to be used with a epidural catheter to provide an ISO 80369-6 NRFit compliant connection.

DASH 6® NRFit Syringe to Syringe Adapter is intended to be used with ISO 80369-6 NRFit neuraxial syringe to allow for mixing/transfering medication between two syringes.

DASH 6® NRFit Needle Hub Cap is intended for sealing the hub of an NRFit compliant needle.

DASH 6® NRFit Epidural Catheter Feeder is intended to be used with ISO 80369-6 NRFit neuraxial compliant devices to assist the insertion of an epidural needle into the epidural space.

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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SECTION 5. 510(K) SUMMARY

This summary of the 510(k) premarket notification for the DASH 6® is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR§807.92.

510(k) Notification K 170900

5.1 GENERAL INFORMATION

Applicant:

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Tel: + 44 (0)1895 347 568

Contact Person:

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Regulatory Affairs Manager, INTERVENE Group Ltd
Phone: +44 (0)1895 347 568
E-mail: htrieu@ivltd.co.uk

Date Prepared: March 27, 2017

5.2 DEVICE INFORMATION

Trade/Proprietary Name:

DASH 6® NRFit: Lock Syringe, Slip Syringe, Plastic LOR Device, Introducer Needle, Syringe Caps, Drawing Up Filter Straw, Blunt Drawing Up Needle (with and without filter), Bacterial Disc Filter, Epidural Flat Filter, Tuohy Borst Adapter, Syringe-Syringe adapter, Needle Hub Cap, Epidural Catheter Feeder

Generic/Common Name:	Syringe Piston
Product Code:	FMF
Device Class and Panel:	Class II, General Hospital
Classification Regulation:	21 CFR§880.5860

Generic/Common Name:	Catheter, Conduction, Anesthetic
Product Code:	BSO
Device Class and Panel:	Class II, Anesthesiology

Generic/Common Name: Needle, Conduction, Anesthetic (W/WO Introducer)

Product Code: BSP

Device Class and Panel: Class II, Anesthesiology

Generic/Common Name: Filter, Conduction, Anesthetic

Product Code: BSN

Device Class and Panel: Class II, Anesthesiology

5.3 PREDICATE DEVICE(S) SYRINGE COMPONENTS

	Primary Predicate: Lock/Slip Syringe	**Reference Device: NRFit Connector**	**Reference Device: Lock/Syringe**
Trade Name	Becton Dickinson Hypodermic Syringe	Tuohy NRFit	CorrectInject safety System
Manufacturer and Clearance Number	Becton, Dickenson and Company K151766	PAJUNK GmbH Medizintechnologie K160297 {Modification of PAJUNK Tuohy Anesthesia Conduction Needles [K040965] to include NRFit connect-ors}	Smiths Medical K110053
Product Code	FMF	BSP	CAZ
Classification Name	Syringe, Piston	Anesthesia Needle	Anesthesia Conduction Kit

	Primary Predicate: LOR Syringe	**Reference Device: NRFit Connector**	**Reference Device: Plastic LOR**
Trade Name	Spectra-LOR Syringe	Tuohy NRFit	Busse Plastic LOR Syringe
Manufacturer and Clearance Number	Spectra medical device, Inc. K081524	PAJUNK GmbH Medizintechnologie K160297 {Modification of PAJUNK Tuohy Anesthesia Conduction Needles [K040965] to include NRFit connect-ors}	Smiths Medical K110053
Product Code	FMF	BSP	CAZ
Classification Name	Syringe, Piston	Anesthesia Needle	Anesthesia Conduction Kit

5.4 PREDICATE DEVICE(S) ACCESSORIES

	Predicate Device: Bacterial Disc Filter	**Predicate Device: Drawing Up Straw with Filter**	**Predicate Device: Epidural Catheter Feeder**	**Predicate Device: Introducer Needle 19G**	**Predicate Device: Tuohy Borst Adapter**
Trade Name	Portex Epidural Filter	5 micron straw filter contained in the Arrow Flextip Plus Closed Tip Epidural Catheter Kit	Thread assist guide contained in the Busse Epidural Catheter Kit	Spinal Introducer Needle contained in the B Braun Spinal Needle Tray	BD Durasafe Variable Extension Combined Spinal Epidural CSE Needle Set//Kit
Manufacturer and Clearance Number	Smiths Medical ASD, Inc. K083451	ARROW International, Inc. K161075, K143581	Busse Hospital Disposables K093920	B. Braun Medical Inc. K112515	Beckton, Dickinson and Company K954953
Product Code	BSN	CAZ	BSO	BSP	CAZ
Classification Name	Anesthesia Conduction Kit	1) Needle, Aspiration and injection, disposable 2) Anesthesia Conduction Kit	Anesthesia Conduction Catheter	Needle, conduction, anesthetic (w/wo introducer)	Anesthesia Conduction kit

	Predicate Device: **Syringe Cap/Needle Hub Caps**	**Predicate Device:** **Blunt Drawing up Needle (with and without filter)**
Trade Name	CorrectInject Safety System (Caps)	1) CorrectInject Safety System (Filter Needle Assembly) 2) B-D Twinpack Syringe filling device.
Manufacturer and Clearance Number	Smiths Medical ASD, Inc. K110053	1) Smiths Medical ASD, Inc. K110053 2) Becton Dickinson. K974006
Product Code	CAZ	1) CAZ 2) FMI
Classification Name	Anesthesia Conduction Kit	1) Anesthesia Conduction Kit 2) Needle, Hyperdermic, Single Lumen.

5.5 INDICATIONS FOR USE

5.5.1 DASH 6 Primary Device

5.5.1.1 DASH 6 Syringe

The DASH 6® NRFit Lock Syringe and DASH 6® NRFit Slip Syringes are intended to be used with ISO 80369-6 NRFit™ neuraxial compliant devices for administration of neuraxial medication or anesthetic.

5.5.1.2 DASH 6 LOR Device

The DASH 6® NRFit Plastic LOR Device is intended to be used with ISO 80369-6 NRFit™ neuraxial compliant epidural needle for locating the epidural space.

5.5.2 DASH® 6 Accessories

5.5.2.1 DASH 6® Introducer Needle

The DASH 6® Introducer Needle is intended to be used with ISO 80369-6 NRFit™ neuraxial compliant spinal needle for guiding the placement of the spinal needle into the arachnoid/epidural space.

5.5.2.2 DASH 6® NRFit Syringe Cap

The DASH 6® NRFit Syringe Cap is intended to be used with ISO 80369-6 NRFit™ neuraxial syringes for sealing the tip of the syringe.

5.5.2.3 DASH 6® NRFit Drawing Up Filter Straw

DASH 6® NRFit Drawing up Straws are intended to be used with ISO 80369-6 NRFit™ neuraxial syringe for the drawing up of neuraxial medication and anesthetic.

5.5.2.4 DASH 6® NRFit Blunt Drawing Up Needle (with and without filter)

DASH 6® NRFit Blunt Drawing Up Needle is intended to be used with ISO 80369-6 NRFit™ neuraxial syringe for the drawing up of neuraxial medication and anesthetic.

5.5.2.5 DASH 6® NRFit Bacterial Disc Filter

The DASH 6® Bacterial Filter is intended to be used with ISO 80369-6 NRFit™ neuraxial compliant devices to ensure aseptic administration of neuraxial medication and anesthetic.

5.5.2.6 DASH 6® NRFit Epidural Flat Filter

The DASH 6® Bacterial Filter is intended to be used with ISO 80369-6 NRFit™ neuraxial compliant devices to ensure aseptic administration of neuraxial medication and anesthetic.

5.5.2.7 DASH 6® NRFit Tuohy-Borst Adapter

The DASH 6® Tuohy-Borst Adapter is intended to be used with a epidural catheter to provide an ISO 80369-6 NRFit™ compliant connection.

5.5.2.8 DASH 6® NRFit Syringe to Syringe Adapter

The DASH 6® syringe to syringe adapter is intended to be used with ISO 80369-6 NRFit™ neuraxial syringe to allow for mixing/transfering medication between two syringes.

5.5.2.9 DASH 6® NRFit Needle Hub Cap

The DASH 6® Needle Hub Cap is intended for sealing the hub of an NRFit™ compliant needle.

5.5.2.10 DASH 6® NRFit Epidural Catheter Feeder

The DASH 6® Epidural Catheter Feeder is intended to be used with ISO 80369-6 NRFit™ neuraxial compliant devices to assist the insertion of an epidural needle into the epidural space.

5.6 PRODUCT DESCRIPTION

Primary Devices

DASH 6 Syringes

The DASH 6® NRFit Syringes (Lock and Slip Syringes) are Single Use, in-hospital devices. They are provided in sizes ranging from 1 mL to 60 mL. The devices incorporate a male NRFit connector for connection to a female NRFit port. The syringes are designed according to ISO 7886-1 & ISO 80369-6 standard. The syringes are used for neuraxial purposes (ISO 80369-6 NRFit connection) and functions exactly the same as any hypodermic syringes that are on the market (ISO 7886-1).

The syringes will be supplied as individually packed (sterile) and the bulk packed (Non-sterile). The Sterile packed items will be supplied directly to the user and the bulk packed will be supplied to Anesthetic Conduction Kit manufacturers to be packaged into kit.

The syringe packaging will indicate the volume/size, the connector type (Lock or Slip variants) that the syringe contains and the sterility/sterilization method the syringe have been processed.

DASH 6 Plastic LOR Devices

The DASH 6® Plastic LOR devices are Single Use, in-hospital devices. It is provided with a 10 mL size/volume and incorporates a male ISO 80369-6 NRFit slip connector to connect to a female ISO 80369-6 NRFit Port.

The Plastic LOR devices are designed according to ISO 80369-6 standard. The syringes are used for neuraxial purposes (ISO 80369-6 NRFit connection) and functions exactly the same as the LOR devices on the market.

The device will be supplied as individually packed (sterile) and the bulk packed (Non-sterile). The Sterile packed items will be supplied directly to the user and the bulk packed will be supplied to Anesthetic Conduction Kit manufacturers to be packaged into kit.

The devices packaging will indicate the volume/size, the connector type (Slip) that the device contains and the sterility/sterilization method the device have been processed.

Accessories

DASH 6® NRFit Syringe Caps

The DASH 6® NRFit Syringe Cap are Single Use, in-hospital devices. It incorporates a female ISO 80369-6 NRFit connector to be connected on an ISO 80369-6 compliant male port.

The device will be supplied as individually packed (sterile) and the bulk packed (Non-sterile). The Sterile packed items will be supplied directly to the user and the bulk packed will be supplied to Anesthetic Conduction Kit manufacturers to be packaged into kit.

The devices packaging will indicate it is a syringe cap and the sterility/sterilization method the device have undergone.

DASH 6® NRFit Drawing up Filter Straw

The DASH 6® NRFit Drawing up Filter Straw are Single Use, in-hospital devices. It incorporates a female ISO 80369-6 NRFit connector to be connected on an ISO 80369-6 compliant NRFit syringe to draw up neuraxial medication and anesthetic.

The device will be supplied as individually packed (sterile) and the bulk packed (Non-sterile). The Sterile packed items will be supplied directly to the user and the bulk packed will be supplied to Anesthetic Conduction Kit manufacturers to be packaged into kit.

The devices packaging will indicate it is a drawing up filter straw and the sterility/sterilization method the device have undergone.

DASH 6® NRFit Blunt Drawing up Needle (with and without filter)

The DASH 6® NRFit Blunt Drawing up Needle (with and without filter) are Single Use, in-hospital devices. It incorporates a female ISO 80369-6 NRFit connector to be connected on an ISO 80369-6 compliant NRFit syringe to draw up neuraxial medication and anesthetic.

The device will be supplied as individually packed (sterile) and the bulk packed (Non-sterile). The Sterile packed items will be supplied directly to the user and the bulk packed will be supplied to Anesthetic Conduction Kit manufacturers to be packaged into kit.

The devices packaging will indicate it is a Blunt Drawing up Needle (with or without filter) and the sterility/sterilization method the device have undergone.

DASH 6® NRFit Bacterial Disc Filter

The DASH 6® NRFit Bacterial Disc Filter is Single Use, in-hospital devices. It incorporates a male & female ISO 80369-6 NRFit connector on the device and a 0.22µm filter in the middle of the housing. The device is to be connected to a female & male ISO 80369-6 NRFit compliant device to ensure aseptic administration of neuraxial medication and anesthetic.

The device will be supplied as individually packed (sterile). The Sterile packed items will be supplied directly to the hospitals.

The devices packaging will indicate it is a bacterial disc filter and the sterility/sterilization method the device have undergone.

DASH 6® NRFit Epidural Flat Filter

The DASH 6® NRFit Epidural Flat Filter is Single Use, in-hospital devices. It incorporates a male & female ISO 80369-6 NRFit connector on the device and a 0.22µm filter in the middle of the housing. The device is to be connected to a female & male ISO 80369-6 NRFit compliant device to ensure aseptic administration of neuraxial medication and anesthetic.

The device will be supplied as individually packed (sterile) and the bulk packed (Non-sterile). The Sterile packed items will be supplied directly to the user and the bulk packed will be supplied to Anesthetic Conduction Kit manufacturers to be packaged into kit.

The devices packaging will indicate it is an Epidural Flat Filter and the sterility/sterilization method the device have undergone.

DASH 6® NRFit Tuohy Borst Adapter

The DASH 6® NRFit Tuohy Borst Adapter is Single Use, in-hospital devices. It incorporates a female ISO 80369-6 NRFit connector to be connected on an ISO 80369-6 NRFit compliant male port and open catheter port, which will allow a epidural catheter to provide an ISO 80369-6 NRFit™ compliant connection.

The device will be supplied as bulk packed (Non-sterile). The bulk packed will be supplied to Anesthetic Conduction Kit manufacturers to be packaged into kit.

The devices packaging will indicate it is a Tuohy borst Adapter and the sterility/sterilization method the device have undergone.

DASH 6® NRFit Needle Hub Caps

The DASH 6® NRFit Needle Hub Cap are Single Use, in-hospital devices. It incorporates a Male ISO 80369-6 NRFit connector to be connected on an ISO 80369-6 compliant female port.

The device will be supplied as individually packed (sterile) and the bulk packed (Non-sterile). The Sterile packed items will be supplied directly to the user and the bulk packed will be supplied to Anesthetic Conduction Kit manufacturers to be packaged into kit.

The devices packaging will indicate it is a Needle Hub cap and the sterility/sterilization method the device have undergone.

DASH 6® Epidural Catheter Feeder.

The DASH 6® Epidural Catheter Feeder are Single Use, in-hospital devices. It incorporates a compatible male ISO 80369-6 NRFit connector to be connected on an ISO 80369-6 compliant female port.

The device will be supplied as bulk packed (Non-sterile). The bulk packed will be supplied to Anesthetic Conduction Kit manufacturers to be packaged into kit.

The devices packaging will indicate it is an Epidural Catheter Feeder and the sterility/sterilization method the device have undergone.

5.6.1 Substantial Equivalence

The indications for use for the (primary) predicates and associated accessories are substantially equivalent to the proposed indications for use for the DASH 6® range of devices and accessories.

The DASH 6 NRFit syringes, BD hypodermic syringes and the syringes placed in the CorrectInject Safety System Kit have the same intended use, operate similarly and have similar materials. The only difference is the technological characteristics of the connection system. The DASH 6® NRFit Syringe is in accordance to ISO 80369-6 compliance and is specified for Neuraxial purposed only. Pajunk Tuohy NRFit Anesthetic Conduction needle is reference to show that the DASH 6® NRFit syringes are developed to comply with ISO 80369-6 NRfit Standard and for this used within the regulation of Anesthesiology.

The DASH 6 NRFit LOR Devices are equivalent to that of the Specta-LOR syringes and Busse Plastic LOR syringe. The LOR device operates the same way as the predicate devices and has the same intended use. The only difference is the technological characteristics of the connection system.

The DASH 6® NRFit Syringe Cap and DASH 6® NRFit Needle Hub Cap are equivalent to that of the Caps supplied in the CorrectInject kit. The accessory operates the same way as the predicate devices and has the same intended use. The only difference is the connection system on the caps.

The DASH 6® NRFit Drawing Up Filter Straw are equivalent to that of B.Braun Filter Straw is currently sold in the US market. Please find the attached link (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm?lid=186755&lpcd=GAA). The filter straw is a class I device itself are exempt from 510k. The devices operates exactly the same way as the predicate device. The 5 Micron Straw Filter listed in the Arrow Epidural Catheter Kit is also used as a reference predicate as the filter straw will be packaged in to an Anesthetic conduction kit. The only difference is the connection system on the connector of the straw hub.

The DASH 6® NRFit Blunt Drawing Up Needle (with and without filter) are equivalent to that of the filter needle supplied in the CorrectInject kit and the twin Pack Syringe filling device supplied by BD. The blunt needle operates the same way as the predicate devices and has the same intended use. The only difference is the connection system on the connector of the needle hub.

The DASH 6® NRFit Bacterial Disc Filter and Epidural Flat Filter are equivalent to that of the Portex supplied in the CorrectInject kit. The filters operated exactly the same way as the predicate devices and has the same intended use. The only difference is the connection system on the housing.

The DASH 6® NRFit Tuohy-Borst Adapter are equivalent to that of the Tuohy borst adaptor supplied in the EpiLong set for Anesthesiology, supplied by Pajunk. The Tuohy borst adapter operated exactly the same way as the predicate devices and has the same intended use. The only difference is the connection system.

DASH 6® NRFit Syringe to Syringe Adapter are a Class I accessory. The connection system contains two female ISO 80369-6 NRFit connectors.

DASH 6® NRFit Epidural Catheter Feeder are equivalent to that of the Thread assist guide contained in the Busse Epidural Catheter Kit. The Epdirual operated exactly the same way as the predicate devices and has the same intended use. The only difference is the connection system on the accessory.

The differences in the technological characteristics between the devices and accessories do not raise any new issues of safety or effectiveness. Thus, the DASH 6® NRFit Syringe device family and accessories (DASH 6® NRFit Syringe Cap, DASH 6® NRFit Drawing Up Straw with Filter, DASH 6® NRFit Blunt Drawing Up Needle (with and without filter), DASH 6® NRFit Bacterial Disc Filter, DASH 6® NRFit Epidural Flat Filter, DASH 6® NRFit Tuohy-Borst Adapter, DASH 6® NRFit Syringe to Syringe Adapter, DASH 6® NRFit Needle Hub Cap, DASH 6® NRFit Epidural Catheter Feeder) are substantially equivalent to their predicate devices.

5.6.2 Testing in Support of Substantial Equivalence Determination

All necessary bench testing was conducted on the DASH 6® Family of devices to support a determination of substantial equivalence to the (primary) predicate and the associated accessories. Testing included biocompatibility, sterilization validation, shipping and packaging, accelerated aging, and design verification testing. Design verification testing included the following:

- Visual inspection
- Dimensional verification
- Physical testing

Performance testing was conducted to confirm compliance to the design specifications of ISO 80369-6; all functions have been verified to operate as designed. The DASH 6® Syringe device family, its male NRFit connector and its accessories (with female NRFit connectors) have met all acceptance criteria, as described in Section 18.

5.6.3 Tests Defined in ISO 80369-6 and 80369-20 for NRFit Connectors

Individual Test Defined in ISO 80369-6	Test Method Defined in ISO 80369-20
Fluid Leakage	Annex C
Stress Cracking	Annex E
Resistance to separation from axial load	Annex F
Resistance to separation from unscrewing	Annex G
Resistance to overriding	Annex H

Dimensional analysis was conducted for critical dimensions of the DASH 6® NRFit Syringe device family and its accessories (with NRFit connectors), in accordance with the criteria in ISO 80369-6.

Device Verification Testing for the piston syringe was conducted in accordance with ISO 7886-1 (Capacity Tolerance, Leakage Testing Side Force, Leakage Testing Axial Force). Cytotoxicity, Sensitization, and Extractables and Leachables testing was also done per ISO 10993-5, 10993-10, and 10993-18 and 10993-19, respectively.

The DASH 6 NRFit plastic LOR device itself did not undergo testing according to due to its intended use. The LOR device is a low friction device and it is used to locate the epidural space. The requirement for low friction and integrity of the seal from the gasket to the barrel is therefore compromised to produce the required clinical function to enable the physician to locate the epidural space. As such, to test the performance for "leakage and resistance" for the LOR device will not be testable under the regime of ISO 7886-1 as it is not applicable.

Design verification testing for the needles were conducted in accordance with ISO 7864-1 but only in certain respects (i.e. Needle to Needle Hub bonding, dimensions tolerances and blockages within the needle). The reason for this is that the DASH 6 NRFit needles are not intend for administering medication. Therefore, certain characteristic aspect of specified in ISO 7864-1, were taken into account for these needles.

Design verification testing were completed on the filter device to ensure that the device is also functioning according to it requirement. This includes the bubble point test, flow-rate and filtration efficiency.

The risk associated with misconnection of the NRFit connector has been assessed and the process captured in the following documents:

- FMEA (Design, User, Process)
- Risk Management Report

The collective results of the testing demonstrate that the DASH 6® NRFit Syringe device family and accessories meet specifications and perform as intended. In addition, the collective bench testing demonstrates that the DASH 6® NRFit Syringe device family and accessories do not raise new questions of safety or effectiveness as compared to the predicate or the associated accessories.

5.7 CONCLUSION

The DASH 6® NRFit Syringe family and accessories have the same intended use and similar technological characteristics as the predicate devices. The DASH 6 NRFit Syringe family and accessories have been tested to ensure that they perform as intended and do not raise new questions of safety or effectiveness. As such, the DASH 6 NRFit Syringe device family and accessories are substantially equivalent to the predicate and the associated accessories.