December 16, 2020

International Medical Industries, Inc.
David Meily
Director of Quality & Regulatory Affairs
2981 Gateway Drive
Pompano Beach, Florida 33069

Re: K201031
Trade/Device Name: NRFit® Caps, Male and Female Neuraxial Tip Caps
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: QEH
Dated: November 18, 2020
Received: November 19, 2020

Dear David Meily:

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,

Rumi Young
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)*
K201031

Device Name
NRFit® Caps, Male and Female Neuraxial Tip Caps

Indications for Use *(Describe)*
The NRFit® cap is a sterile, single-use device intended to provide positive closure to prevent fluid loss and contamination in Neuraxial devices CADD Cassettes or Syringes utilizing NRFit® connections. The NRFit® cap is intended to be used for less than 24 hours on any single application.

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
NRFit® Caps, Male and Female Neuraxial Tip Caps

K201031

1. Submission Sponsor

International Medical Industries, Inc.

2981 Gateway Drive.

Pompano Beach

FL, 33069

USA

Contact: David Meily

Title: Director of Quality & Regulatory Affairs

2. Submission Correspondent

No applicable

3. Date Prepared

December 16, 2020

4. Device Identification

Trade/Proprietary Name:	NRFit® Caps, Male and Female Neuraxial Tip Caps
Common/Usual Name:	syringe, piston
Classification Name:	syringe, piston
Regulation Number:	21 CFR§880.5860
Product Code:	QEH
Device Class:	Class II
Classification Panel:	General Hospital

5. Legally Marketed Predicate Device(s)

Predicate Device

K170900

Trade/Proprietary Name: DASH 6® NRFit Syringe Cap

Common/Usual Name: syringe, Piston

Classification Name: syringe, piston

Regulation Number: 21 CFR 880.5860

Product Code: FMF

Device Class: Class II

Classification Panel: General Hospital

6. Indication for Use Statement

The NRFit® cap is a sterile, single-use device intended to provide positive closure to prevent fluid loss and contamination in Neuraxial devices CADD Cassettes or Syringes utilizing NRFit® connections.

NRFit® cap is intended to be used for less than 24 hours on any single application.

7. Device Description

The NRFit® Caps (abbreviated as "NRFit") are ISO 80369-6 compliant caps designed to prevent fluid loss in Neuraxial devices. The NRFit cap is made from medical grade polypropylene with yellow colorant. The NRFit cap is available with either a male neuraxial lock connection or a female neuraxial lock connection. The NRFit cap is made of materials appropriate for a limited exposure duration, externally communicating, tissue/bone/dentin contacting medical device.

8. Substantial Equivalence Discussion

Based on the above information and FDA Guidance Document "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications", the proposed NRFit caps is concluded to be substantially equivalent to its predicate, DASH 6 NRFit syringe caps.

Table 5-A: NRFit Caps and Predicate Device Comparison

Manufacturer	International Medical Industries, Inc.	INTERVENE Group Limited	
Proprietary Device Name	NRFit® Caps, Male and Female Neuraxial Tip Caps	DASH 6® NRFit™ Syringe Caps	Comparison
510(k) #	K201031	K170900	N/A
Indications for Use	The NRFit® cap is a sterile, single-use device intended to provide positive closure to prevent fluid loss and contamination in Neuraxial devices CADD Cassettes	DASH 6® NRFit Syringe cap is intended to be used with ISO 80369-6 NRFit neuraxial syringes for sealing the tip of the syringe.	Similar, both are used with neuraxial devices

Manufacturer	International Medical Industries, Inc.	INTERVENE Group Limited	
Proprietary Device Name	NRFit® Caps, Male and Female Neuraxial Tip Caps	DASH 6® NRFit™ Syringe Caps	Comparison
	or Syringes utilizing NRFit® connections. NRFit® cap is intended to be used for less than 24 hours on any single application.		
Product Code	QEH	FMF	New product code for neuraxial devices
Regulation No.	21 CFR 880.5860	21 CFR 880.5860	Same
Classification	Class II	Class II	Same
Device Description	The NRFit® Caps are ISO 80369-6 compliant caps designed to prevent fluid loss in Neuraxial devices. The NRFit® cap is made from medical grade polypropylene with yellow colorant. The NRFit® cap is available with either a male neuraxial lock connection or a female neuraxial lock connection. The NRFit® cap is made of materials appropriate for a limited exposure duration, externally communicating, tissue/bone/dentin contacting medical device < 24 contact duration	DASH 6® NRFit Syringe Caps 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 has undergone.	Similar. IMI's description is based on function, material composition and patient contact. INTERVENE's description is of packaging and sterility. Both companies agree on compliance to ISO 80369-6
Environment	General Hospital	General Hospital	Same
User	Hospital/clinical personnel	Hospital/clinical personnel	Same
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Same
Number of Uses	Single Use	Single Use	Same
Cap Material	Polypropylene (PP)	Polypropylene (PP)	Same
Biocompatibility Contact and Duration	External communicating, blood path (indirect) for a duration of ≤24 Hrs.	External communicating, blood path (indirect) for a duration of ≤24 Hrs.	Same

The predicate device is a Syringe Family and Accessories. The NRFit® caps are substantially equivalent to the accessory- DASH 6® NRFit Syringe caps.

Note: Based on the comparison above, there are no new or different questions of safety or effectiveness.

9. Non-Clinical Performance Data

Table 5-B: Summary of NRFit® Caps Testing

Test Name	Test Description
Falling Drop Liquid Leakage	NRFit® device shall show no signs of leakage sufficient to form a falling drop of water
Sub-atmospheric-pressure air leakage	NRFit® Device shall not leak by more than 0.005 Pa·(m^3)/s during aspiration
Stress Cracking	NRFit® Device shall show no evidence of stress cracking (i.e. visible cracks in the threads or taper of the connector) or leakage after Stress Crack testing
Axial Separation	NRFit® Device shall not separate from a properly installed reference connector while being subjected to at least 35N disconnection tensile axial force
Resistance to Unscrewing	NRFit® Device shall not separate from a properly installed reference connector
Resistance to Overriding	NRFit® device shall not override the threads or lugs of the reference connector
Visual	NRFit® device shall be a similar yellow in color to other NRFit products available on the open market
Visual Inspection	Device must be available in a primary package blister configuration consisting of PETG film with Tyvek Lid.
Visual Inspection	Heat seals must meet ASTM F1886:2013 Standard test method for determining integrity of seals for flexible packaging by visual inspection
Wearing a set of disposable nitrile gloves, run a finger along the outer edge of the packaging and ensure glove does not catch on any feature such that a hole or tear is formed	Primary packaging must not expose the user to sharps that may cause injury or a breach in aseptic technique
Visual Inspection	Product outer packaging must be free from gross cosmetic defects, particulate, and foreign material
Transportation, Shelf Life	Simulated transportation conditions and shelf life followed by design verification testing.
Product Validation	Human factors and Usability
Biocompatibility	Cytotoxicity, Intracutaneous Irritation testing, Sensitization testing, Hemolysis testing direct/indirect, Acute systemic toxicity, Pyrogenicity, Chemical Characterization, Extractables and Leachables, Toxicological Risk assessment.
Performance	ISO 80369-6:2016 and ISO 80369-20:2015

10. Clinical Performance Data

There was no human clinical testing required to support the medical device as the indications for use is equivalent to the predicate device.

11. Statement of Substantial Equivalence

The male and female NRFit® caps have the same intended use, function, materials and patient contact as the predicate device. Both devices are compliant to ISO 80369-6. Minor technological differences do not raise new or different questions of safety and effectiveness.
The NRFit® caps, as designed and manufactured, are determined to be substantially equivalent to the referenced predicate device.