October 20, 2017

Intervene Group Limited
Homer Trieu
Regulatory Affairs Manager
Russell Building, Brunel Science Park, Kingston Lane
Uxbridge, UB8 3PQ GB

Re: K170371
Trade/Device Name: Dash 3 ENFit Syringe, Dash 3 Eccentric ENFit Syringe, Dash 3 ENFit Low Dose Tip Syringe, Dash 3 ENFit Syringe Cap.
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: Class II
Product Code: PNR
Dated: September 11, 2017
Received: September 25, 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Joyce M. Whang -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological 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)*
K170371

Device Name
DASH 3™ ENFit Syringe, DASH 3™ Eccentric ENFit Syringe, DASH 3™ ENFit Low Dose Tip Syringe, DASH 3™ ENFit Syringe Cap

Indications for Use *(Describe)*
The DASH 3™ ENFit Syringe is a single use syringe indicated for use as a dispenser, a measuring device, and a fluid transfer device. It is used to deliver fluids or nutritional formula into the gastrointestinal system of a patient who is physically unable to eat and swallow. The enteral syringes are intended to be used in clinical or home care settings by users ranging from laypersons (under the supervision of a clinician) to clinicians, in all age groups.

The DASH 3™ Eccentric ENFit Syringe is a single use syringe indicated for use as a dispenser, a measuring device, and a fluid transfer device. It is used to deliver fluids or nutritional formula into the gastrointestinal system of a patient who is physically unable to eat and swallow. The enteral syringes are intended to be used in clinical or home care settings by users ranging from laypersons (under the supervision of a clinician) to clinicians, in all age groups.

The DASH 3™ Low Volume Tip ENFit Syringe is a single use syringe indicated for use as a dispenser, a measuring device, and a fluid transfer device. It is used to deliver fluids or nutritional formula into the gastrointestinal system of a patient who is physically unable to eat and swallow. The enteral syringes are intended to be used in clinical or home care settings by users ranging from laypersons (under the supervision of a clinician) to clinicians, in all age groups.

Accessories

The DASH 3™ ENFit Syringe Cap allows the advance preparation and secure storage and transport of medication/fluids or nutritional formula. The syringe cap will fit any size of the Single Use Syringes (DASH 3™)

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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SECTION 5 510(K) SUMMARY

This summary of the 510(k) premarket notification for the DASH 3™ is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR§807.92.

5.1 General Information

Applicant:
INTERVENE Group Ltd.
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Contact Person:
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Phone: +44 (0) 0207 841 2735
E-mail: htrieu@ivltd.co.uk
Date Prepared: February 6, 2017

5.2 Device Information

Trade/Proprietary Name:

DASH 3™ ENFit Syringe, DASH 3™ Eccentric ENFit Syringe, DASH 3™ ENFit Low Dose Tip Syringe, DASH 3™ ENFit Syringe Cap.

Generic/Common Name:	Enteral syringes with enteral specific connectors (syringes) Gastrointestinal tubes with enteral specific connectors (accessories)
Product Code:	PNR (syringes)
Device Class and Panel:	Class II, Gastroenterology and Urology
Classification Regulation:	21 CFR§876.5980 - Gastrointestinal tube and accessories.

5.3 Predicate Device/Reference devices in the market

5.3.1 Predicate for Syringes

	Primary Predicate: Centered Tip Syringe and Low Dose Tip Syringe	Reference Device: Eccentric Syringe Tip
Trade Name:	Monoject Enteral Feeding Syringe with ENFit Connector	NeoConnect Oral/Enteral Syringes with ENFit Connectors
Manufacturer and Clearance Number:	Covidien K161963 K161045	NeoMed, Inc. K161039
Product Code:	PNR	PNR
Classification Name:	Enteral Syringes with Enteral Specific Connectors	Enteral Syringes with Enteral Specific Connectors

5.3.2 Predicate/Reference for Accessories

	Predicate: Syringe Cap
Trade Name:	NeoMed NeoConnect™ Enteral Syringes with ENFit™ Connector and compatible NeoSecure™ Tip Caps
Manufacturer and Clearance Number:	NeoMed, Inc. K152857
Product Code:	PIF
Classification Name:	Gastrointestinal Tube and accessories

5.4 Indications for Use

Syringes

The DASH 3™ ENFit Syringe is a single use syringe indicated for use as a dispenser, a measuring device, and a fluid transfer device. It is used to deliver fluids or nutritional formula into the gastrointestinal system of a patient who is physically unable to eat and swallow. The enteral syringes are intended to be used in clinical or home care settings by users ranging from laypersons (under the supervision of a clinician) to clinicians, in all age groups.

The DASH 3™ Eccentric ENFit Syringe is a single use syringe indicated for use as a dispenser, a measuring device, and a fluid transfer device. It is used to deliver fluids or nutritional formula into the gastrointestinal system of a patient who is physically unable to eat and swallow. The enteral syringes are intended to be used in clinical or home care settings by users ranging from laypersons (under the supervision of a clinician) to clinicians, in all age groups.

The DASH 3™ Low Dose Tip ENFit Syringe is a single use syringe indicated for use as a dispenser, a measuring device, and a fluid transfer device. It is used to deliver fluids or nutritional formula into the gastrointestinal system of a patient who is physically unable to eat and swallow. The enteral syringes are intended to be used in clinical or home care settings by users ranging from laypersons (under the supervision of a clinician) to clinicians, in all age groups.

Accessories

The DASH 3™ ENFit Syringe Cap allows the advance preparation and secure storage and transport of medication/fluids or nutritional formula. The syringe cap will fit any size of the Single Use Syringes (DASH 3™).

5.5 Product Description

The DASH 3™ ENFit Syringe device family is a Single Use, in-hospital and home care (DASH 3™ ENFit Syringe, DASH 3™ Eccentric ENFit Syringe, DASH 3™ ENFit Low Dose Tip Syringe) device.

It is provided in sizes from 1 mL to 100 mL. The device incorporates a female ENFit connector for connection to an enteral access device with a male ENFit port specified in ISO 80369-3. The Low Dose Tip contains the low dose design feature specified in (Draft) ISO 20695.

The DASH 3™ ENFit accessories are designed to be compatible with ENFit connector devices. The DASH 3™ ENFit Syringe Caps fit any size of the Single Use ENFit Syringes (DASH 3™), which allows the advance preparation and secure storage and transport of medication/fluids or nutritional formula.

5.6 Substantial Equivalence

The indications for use for the (primary) predicate and reference devices are substantially equivalent to the proposed indications for use for the DASH 3™ ENFit Syringe, DASH 3™ Eccentric ENFit Syringe, DASH 3™ ENFit Low Dose Tip Syringe and DASH 3™ ENFit Syringe Cap. Both device families have the same intended use and similar technological characteristics. Any differences in the technological characteristics between the devices do not raise any new issues of safety or effectiveness. These differences can be from non-critical dimensions (i.e. barrel wings, plunger dimension), additional sizes (i.e. 100ml Syringe), the color of the devices and packaging arrangements. Thus, the DASH 3™ ENFit Syringe device family and accessories are substantially equivalent to the predicate and reference devices.

5.7 Testing in Support of Substantial Equivalence Determination

All necessary bench testing was conducted on the DASH 3™ ENFit Syringe, DASH 3™ Eccentric ENFit Syringe, DASH 3™ ENFit Low Dose Tip Syringe and DASH 3™ ENFit Syringe Cap to support a determination of substantial equivalence to the (primary) predicate and reference devices. 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 80369-3, and also with reference to Draft ISO 20695 for the low dose tip; all functions have been verified to operate as designed. The DASH 3™ Syringe device

family, its female ENFit connector and its accessories (with male ENFit connectors) have met all acceptance criteria, as described in Section 17.

Tests Defined in ISO 80369-3 and 80369-20 for ENFit Connectors

Individual Test Defined in ISO 80369-3	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
Disconnection by unscrewing	Annex I

Dimensional analysis was conducted for critical dimensions of the DASH 3™ ENFit Syringe device family and its accessories (with ENFit connectors), in accordance with the criteria in ISO 80369-3.

Device Verification Testing for the piston syringe was conducted in accordance with ISO 7886-1. This includes:

- Lubricant,
- Limits of extractable metals,
- Limits for acidity/alkalinity,
- Capacity Tolerance (Graduated Scale),
- Dead Space
- Air and liquid leakage Testing (Side Force/Axial Force.)

Biocompatibility testing has demonstrated that the DASH 3™ Syringe and its accessories meet the requirements for biocompatibility.

Stability testing evaluated the properties of the DASH 3™ Syringe and its accessories after accelerated aging to establish a 5-year shelf life for the syringes and a 3 to 5-year shelf life for the accessories and to confirm the strength and integrity characteristics of the sterile device packaging and the ability of the packaging to maintain a sterile barrier for the duration of the labeled shelf life.

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

- FMEA (Design, User, Process)
- Risk Management Report
- Enteral Connector Misconnection Assessment (As recommended in FDA Enteral Connector Guidance)

Additional testing for the Low Dose Syringe tip design includes:

- Low Dose Enteral Connector Misconnection Assessment (As recommended in FDA Enteral Connector Guidance)
- Usability Assessment for the Low Dose Syringe Tip Design
- Low Dose Syringe Design Dose Accuracy Testing

The collective results of the testing demonstrate that the DASH 3™ ENFit Syringe device family and accessories meet specifications and perform as intended. In addition, the collective bench testing demonstrates that the DASH 3™ ENFit Syringe device family and accessories do not raise new questions of safety or effectiveness as compared to the predicate or reference devices.

5.8 Conclusion

The DASH 3™ ENFit Syringe family and accessories have the same intended use and similar technological characteristics as the predicate devices. The DASH 3™ ENFit 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 3™ ENFit Syringe device family and accessories are substantially equivalent to the predicate and reference devices.