DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 22, 2016

VR Medical Technology Company
% Korina A. Akhondzadeh
Regulatory Consultant to VR Medical Technology
KARA & Associates
6965 El Camino Real, Suite 105-428
Carlsbad, CA 92009

Re: K162188
Trade/Device Name: Enteral Syringe with ENFit® Connector (10 ml to 60 ml),
Enteral Syringe with ENFit® Low Dose Tip (1 ml To 5 ml)
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: II
Product Code: PNR
Dated: August 1, 2016
Received: August 4, 2016

Dear Korina A. Akhondzadeh:

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 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 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)*

K162188

Device Name

Enteral Syringe with ENFit® Connector (10 ml to 60 ml)
Enteral Syringe with ENFit® Low Dose Tip (1 ml to 5 ml)

Indications for Use *(Describe)*

The device is indicated for use as a dispenser, a measuring device and a fluid transfer device. It is used to deliver fluids into the body enterally. It is intended to be used in clinical or home care settings by users ranging from clinicians to laypersons (under the supervision of a clinician) for patients in all age groups.

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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510(k) Summary

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

I. SUBMITTER

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Date Prepared: August 1, 2016

II. DEVICE

Device Name:	Enteral Syringe with ENFit Connector (10 ml to 60 ml) and Enteral Syringe with ENFit Low Dose Tip (1 ml to 5 ml)
Common/Usual Name:	Enteral Syringe
Classification Name:	Gastrointestinal tube and accessories
Product Code:	PNR
Class:	II

III. PREDICATE DEVICE

Predicate Device
Neoconnect Oral/Enteral Syringes with ENFit Connector (12 mL to 100 mL) and NeoConnect Low Dose Tip Oral/Enteral Syringes with ENFit Connector (0.5 mL to 6 mL), K161039

This predicate device has not been subject to a recall.

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IV. DEVICE DESCRIPTION

The Enteral Syringe with ENFit Connector (10 ml to 60 ml) and the Enteral Syringe with ENFit Low Dose Tip (1 ml to 5 ml) are both sterile or non-sterile, standard piston style enteral syringes with an integrated female ENFit compatible connector compliant to the requirements of ISO DIS 80369-3, First Edition, Small-bore Connectors for Liquids and Gases in Healthcare Applications – Part 3: Connectors for Enteral Applications and designed to be compatible with male ENFit connectors.

The Enteral Syringe with ENFit Connector has capacities of 10, 20, 30 and 60 ml and is available in two different connector configurations: Centerline and Offset.

The Enteral Syringe with ENFit Low Dose Tip is a low dose syringe and has capacities of 1, 3 and 5 ml. The ENFit Lose Dose tip is a modification of the ENFit connector designed for the delivery of low doses of fluids for enteral feeding.

V. INDICATIONS FOR USE

The device is indicated for use as a dispenser, a measuring device and a fluid transfer device. It is used to deliver fluids into the body enterally. It is intended to be used in clinical or home care settings by users ranging from clinicians to laypersons (under the supervision of a clinician) for patients in all age groups.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Both the subject Enteral Syringe with ENFit Connector (10 ml to 60 ml) and Enteral Syringe with ENFit Low Dose Tip (1 ml to 5 ml) devices and predicate Oral/Enteral Syringes with ENFit Connector (12 ml to 100 ml) and Low Dose Tip Oral/Enteral Syringes with ENFit Connector (0.5 ml to 6 ml) devices are a standard piston-style syringe with an integral female ENFit Connector. The ENFit Connector for both the VR Medical and NeoMed devices were designed to be compliant with ISO DIS 80369-3, First Edition, Small-bore Connectors for Liquids and Gases in Healthcare Applications – Part 3: Connectors for Enteral Applications.

Both the Enteral Syringe with ENFit Low Dose Tip (1 ml to 5 ml) and predicate Low Dose Tip Oral/Enteral Syringes with ENFit Connector (0.5 ml to 6 ml) incorporate the same ENFit low dose tip design to ensure accuracy when dispensing small volumes.

The ENFit connectors on both the subject and predicate devices are compatible only with enteral access devices or accessories having ENFit compliant or compatible male connectors to prevent misconnections to non-enteral devices. Both the subject and predicate devices are available in both sterile and non-sterile versions.

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VII. PERFORMANCE DATA

The following performance testing was conducted on the Enteral Syringe with ENFit Connector (10 ml to 60 ml) and the Enteral Syringe with ENFit Low Dose Tip (1 ml to 5 ml).

Biocompatibility Testing

- Cytotoxicity per ISO 10993-5
- Sensitization per ISO 10993-10
- Irritation per ISO 10993-10

Performance Testing

Tests per ISO 7886-1:

Cleanliness
Lubricant
Position of scale
Tolerance on graduated capacity
Dead space
Fit of piston in barrel
Slide force test
Freedom from air and liquid leakage
Limits for acidity or alkalinity
Limits of extractable metals

Tests per ISO DIS 80369-3:

Dimensional verification
Positive pressure liquid leakage
Stress cracking
Resistance to separation from axial load
Resistance to separaion from unscrewing
Resistance to overriding
Disconnection by unscrewing

Printing Firmness

For the Enteral Syringe with ENFit Connector

- Risk Assessment per ISO 14971

For the Enteral Syringe with ENFit Low Dose Tip

- Low Dose Tip Misconnection Risk Management Reports
- Usability Study for Low Dose Tip Design Feature

VIII. CONCLUSIONS

The Enteral Syringe with ENFit Connector (10 to 60 ml) and the Enteral Syringe with ENFit Low Dose Tip (1 to 5 ml) are substantially equivalent to the predicate Oral/Enteral Syringes with ENFit Connector (12 ml to 100 ml) and Low Dose Tip Oral/Enteral Syringes with ENFit Connector (0.5 ml to 6 ml) devices.