January 18, 2019

VR Medical Technology Co., Ltd
% Paul E. Dryden
Consultant
VR Medical c/o ProMedic, LLC
131 Bay Point Dr. NE
St. Petersburg, FL 33704

Re: K180236
Trade/Device Name: VR Medical Feeding Tube and Enteral Feeding Extension Set (EFES)
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: II
Product Code: FPD, KNT, PIF
Dated: December 7, 2018
Received: December 10, 2018

Dear Paul E. Dryden:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Daniel G. Walter Jr -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K180236

Device Name

VR Medical Feeding Tube and Enteral Feeding Extension Set (EFES)

Indications for Use *(Describe)*

The VR Medical Feeding Tube is intended for nasogastric or orogastric delivery of various types of liquid nutritional media through the gastro intestinal tract of neonatal and small pediatric patients, and is not intended for use beyond 30 days.

The Enteral Feeding Extension Set (EFES) is intended for use as an extension set for nasogastric / oralgastric or gastric tube enteral feeding tubes, incorporating safety connectors/small bore connectors which are intended to reduce the misconnection between the following applications: I.V. system and Enteral Feeding System.

The EFES is indicated for use in neonatal and pediatric patients in connection with an enteral feeding tube to provide nutrition via nasal or oral gastric placements.

Type of Use *(Select one or both, as applicable)*

XX 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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VR Medical

510(k) Summary

Date Prepared: 11-Jan-2019

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Official Contact: Lee Pan, Ph.D., CEO

Proprietary or Trade Name: VR Medical Feeding Tube and
Enteral Feeding Extension Set (EFES)

Common/Usual Name: Tubes, Gastrointestinal (And Accessories)

Classification Name: Gastrointestinal Tube and Accessories

Classification Details: 21CFR 876.5980
FPD, KNT, PIF
Class II

Predicate Devices: K100526 – Kentec Enteral Feeding Tube
K150084 – Covidien Argyle PVC Enteral Feeding Tubes
K120272 – Kentec Enteral Feeding Tube Extension Sets

Device Description:

Enteral Feeding Tube

The VR Medical Feeding Tube is intended for nasogastric or orogastric delivery of various types of liquid nutritional media through the gastro intestinal tract of neonatal, pediatric and is not intended for use beyond 30 days.

They are sterile, individually packaged. The orange color coding provides easy visual recognition of the enteral connection. They are designed with a radiopaque stripe for X-ray visualization to confirm proper feeding tube placement. They are marked with French size and markings to assist tube placement or check for migration. A tethered plug for connector closure is incorporated when not in use.

Enteral Feeding Extension Sets

The Enteral Feeding Extension Sets (“EFES”) are intended to provide access from the feeding tube to a syringe or nutritional source accepting a connector for enteral applications. They are available in multiple configurations: with and without an in-line Y port and lengths.

The EFES are sterile disposable device for single patient use only. The EFES is designed to connect existing feeding tubes (nasogastric, orogastric, gastric, etc.) to various delivery enteral syringes as well as to help minimize the potential for inadvertent delivery of enteral feedings through the intravenous route. i.e., the device cannot be connected to a luer connector

The EFES consists of flexible tubing with an orange strip for easy quick identification of enteral feeding lines as well as a “For Enteral Feeding Only” tag and a slide clamp to provide the additional safety assurance for connection errors.

Indications for Use:

The VR Medical Feeding Tube is intended for nasogastric or orogastric delivery of various types of liquid nutritional media through the gastro intestinal tract of neonatal and small pediatric patients, and is not intended for use beyond 30 days.

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The Enteral Feeding Extension Set (EFES) is intended for use as an extension set for nasogastric / oralgastric or gastric tube enteral feeding tubes, incorporating safety connectors/small bore connectors which are intended to reduce the misconnection between the following applications: I.V. system and Enteral Feeding System.

The EFES is indicated for use in neonatal and pediatric patients in connection with an enteral feeding tube to provide nutrition via nasal or oral gastric placements.

Patient Population:
Neonate and pediatric patients.

Environments of use:
Hospital, sub-acute care and home settings.

Comparison to Predicates
Enteral Feeding Tube Comparison
The VR Medical Feeding Tube and Enteral Feeding Extension Set are substantially equivalent to the predicate devices, based upon the similar indications for use and similar technological characteristics.

Table 1 - Substantial Equivalence Comparison Table – VR Medical Feeding Tube and Enteral Feeding Extension Set to the predicate devices summarizes the comparison of the VR Medical subject devices to the predicate devices.

Table 1 - Substantial Equivalence Comparison Table – VR Medical Feeding Tube to the Predicate Enteral Feeding Tube Devices

INDICATIONS FOR USE SUBSTANTIAL EQUIVALENCY COMPARISON			
Characteristics	**VR Medical Feeding Tube**	**Kentec Enteral PU Feeding Tube (K100526)**	**Arygle PVC Feeding Tube (K150084)**
Indications for Use	The device is intended for nasogastric or orogastric delivery of various types of liquid nutritional media through the gastro intestinal tract of neonatal and small pediatric patients	The device is intended for nasogastric or orogastric delivery of various types of liquid nutritional media through the gastro intestinal tract of neonatal and small pediatric patients	The device is intended for enteral feeding to deliver enteral nutrition, liquid or medication to patient from an enteral feeding syringe or feeding set designed with a connector for enteral application. The device is intended for pediatric patients who require enteral feeding.
Regulation Number and Product Code	21CFR 876.5980 Product Code: FPD	21CFR 876.5980 Product Code: FPD	21CFR 876.5980 Product Code: PIF
Single-Patient Use	Yes	Yes	Yes
Disposable	Yes	Yes	Yes
Sterile	Yes	Yes	Yes
Use Environment	Hospital or environments where placement of a feeding tube is required.	Hospital or environments where placement of a feeding tube is required.	Hospital or environments where placement of a feeding tube is required.
Patient Population	Neonatal and pediatric patients	Neonatal and pediatric patients	Neonatal and pediatric patients
Feeding Tube	Polyurethane (PU)	Polyurethane (PU)	NA
	Polyvinyl Chloride (PVC)	No	Polyvinyl Chloride (PVC)
Small Bore (ENFit) Connector, Cap and Y Connector Base	Yes	Yes ENFit not part of submission	Yes

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TECHNICAL CHARACTERISTICS FOR SUBSTANTIAL EQUIVALENCY COMPARISON			
A single lumen catheter Sizes	French sizes – (4 – 12 Fr) Lengths - (40 - 110 cm)	French sizes – (4 – 12 Fr) Lengths - (40 - 110 cm)	French sizes - (3.5- 10 Fr) Lengths - (31 to 107 cm)
Oral Connector	Yes	Yes	Yes
ENFit Connector	Yes	Not in the original file	Yes
Cap	Yes	Yes	Yes
Provided Sterile	Yes (ETO Sterilization)	Yes (ETO Sterilization)	Yes
Connector Design Compliant to ISO 80369-3	ENFIT Connector	ENFIT Connector	ENFIT Connector
Performance Testing per ISO 80369-3	Connector performance	Connector performance	Yes
Performance Testing Per EN1615	Tensile strength Tubing Connector to tubing Assembled connector Leakage Flow rate Priming volume Radiopacity	Yes	Yes
Biocompatibility ISO 10993-1	Surface Contacting. Mucosal membrane, Prolonged duration Cytotoxicity, Sensitization, Irritation. Acute systemic and Sub-acute toxicity, Implantation (14 day) and Pyrogenicity	Surface Contacting. Mucosal membrane, Prolonged duration Cytotoxicity, Sensitization, Irritation	Surface Contacting, Mucosal membrane, Prolonged duration

Substantial Equivalence Discussion for Enteral Feeding Tubes
The VR Medical Feeding Tube and the predicate devices have similar indications for use.

Both the subject and predicate devices are prescription, sterile, disposable and single use devices intended for enteral use to provide nutrition/liquids via nasal or oral gastric placement.

Both the subject and predicate devices have similar use environment and patient populations. Both are intended to be used at Hospital or environments where placement of a feeding tube is required for neonatal and pediatric patients.

Comparison of the Enteral Feeding Tube to the Predicate Device for Component and Materials
The subject devices have similar materials and components and construction.

Comparison of the Enteral Feeding Tube to the Predicate Device for Technological Characteristics
Both the VR Medical Enteral Feeding Tube and Predicate Feeding Tube devices have a single lumen catheter with connector that is designed to be compatible only with enteral access devices or accessories. Both the subject and predicate devices are sterile, individual packaged, and available in various sizes.

The performance of the subject device has been established in performance testing conducted in accordance with ISO 80369-3 and EN1615.

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Enteral Feeding Extension Set Substantial Equivalence Comparison

The Enteral Feeding Extension Sets are substantially equivalent to the predicate device, based upon the same intended use and indications for use, and similar technological characteristics.

Table 2 summarizes the comparison of the VR Medical subject devices to the predicate device in terms of intended use and technological characteristics.

Table 2 - Substantial Equivalence Comparison Table –Enteral Feeding Extension Sets to the Predicate

Comparison Table – VR Medical Enteral Feeding Extension Sets to the Predicate		
Characteristics	**VR Medical Enteral Feeding Tube Extension Set**	**Kentec Enteral Feeding Tube Extension Set (K120272)**
Indications for Use	The Enteral Feeding Extension Set (EFES) is intended for use as an extension set for nasogastric / oral gastric or gastric tube enteral feeding tubes, incorporating safety connectors/small bore connectors which are intended to reduce the misconnection between the following applications: I.V. system and Enteral Feeding System. The EFES is indicated for use in neonatal and pediatric patients in connection with an enteral feeding tube to provide nutrition via nasal or oralgastric placements.	The Ameritus® Enteral Feeding Extension Set is intended for use as an extension set for nasogastric/oralgastric or gastric tube enteral feeding tubes, incorporating safety connectors which help mitigate the risk of accidental misconnection with an IV system to the enteral system or the enteral system to an IV system.
Single-Patient Use	Yes	Yes
Disposable	Yes	Yes
Sterile	Yes	Yes
Use Environment	Hospital or environments where placement of a feeding tube is required.	Hospital or environments where placement of a feeding tube is required.
Patient Population	Neonatal and pediatric patients	Neonatal and pediatric patients
COMPONENT AND MATERIALS FOR SUBSTANTIAL EQUIVALENCY COMPARISON		
Characteristics	**VR Medical Enteral Feeding Tube Extension Set**	**Kentec Enteral Feeding Tube Extension Set (K120272)**
Tubing	Polyvinyl Chloride (PVC)	Polyvinyl Chloride (PVC)
Lengths	22” to 60”	22” to 60”
Connectors	Male / Female	Male / Female
Slides	Yes	Yes
Performance Testing per ISO 80369-3	Connector Compatibility Connector Performance	Yes
Performance Testing Per EN1615	Tensile Property Test of tubing Tensile Property Test of bonding Liquid Leakage Test Internal Capacity Test Flow Rate Test	EN 1615
Biocompatibility ISO 10993-1	Surface Contacting. Mucosal membrane, Prolonged duration Cytotoxicity, Sensitization, Irritation. Acute systemic and Sub-acute toxicity, Implantation (14 day) and Pyrogenicity	Externally Communicating, Mucosal membrane, Prolonged duration Cytotoxicity ,Sensitization, Irritation

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The VR Medical Enteral Feeding Tube Extension Sets and the predicate devices both have similar indications for use.

Both the subject and predicate devices have similar use environment and patient populations. Both are intended to be used at Hospital or environments where placement of a feeding tube is required for neonatal and pediatric patients.

Comparison of the Enteral Feeding Extension Set to the Predicate Device for Component and Materials
The subject devices have similar materials and components and construction.

Comparison of the Enteral Feeding Extension Set to the Predicate Device for Technological Characteristics
Both the Enteral Feeding Tube Extension Sets and Predicate are tubing with connectors that allow connection between the solutions and the Feeding Tube. Both the subject and predicate devices are supplied sterile, individual packaged, and available in various lengths and configurations.

The performance of the subject device has been established in performance testing conducted in accordance with ISO 80369-3 and EN 1615.

Summary of Performance Testing
Non-clinical Bench Testing

Enteral Feeding Tube and Extension Set have been tested using the following standards:

ISO 80369-3, First Edition, Small-bore Connectors for Liquids and Gases in Healthcare Applications – Part 3: Connectors for Enteral Applications

ISO 80369-20, First Edition, Small-bore Connectors for Liquids and Gases in Healthcare Applications – Part 20: Common Test Methods

ISO 80369-1, Small-bore Connectors for Liquids and Gases in Healthcare Applications – Part 1: General requirements

EN1615: 2000, Enteral feeding catheters and enteral giving sets for single use and their connectors-Design and testing

ANSI/AAMI ID54:1996/(R) 2012, “Enteral feeding set adapters and connectors”

EN1618:1997 Catheters other than intravascular catheters-Test methods for common properties

The following performance testing of the Enteral Feeding Tube (EFT) was conducted.

a. Connector Compatibility Test in accordance with section 4.2.1 of EN1615: 2000 Enteral feeding catheters and enteral giving sets for single use and their connectors-Design and Testing and ANSI/AAMI ID54: 1996/(R) 2012 Enteral feeding set adapters and connectors.
b. Tensile Property Test of tubing in accordance with section 4.2.2.1 of EN1615: 2000 Enteral feeding catheters and enteral giving sets for single use and their connectors-Design and testing.
c. Tensile Property Test of bonding between connectors and tubing in accordance with section 4.2.2.1 of EN1615: 2000 Enteral feeding catheters and enteral giving sets for single use and their connectors-Design and testing.

d. Liquid Leakage Test in accordance with section 4.3.2 of EN1615: 2000 Enteral feeding catheters and enteral giving sets for single use and their connectors-Design and testing.
e. Tensile Property test of Assembled connection of connectors in accordance with section 4.3.1 of EN1615: 2000 Enteral feeding catheters and enteral giving sets for single use and their connectors-Design and testing.
f. Connector Performance test in accordance with ISO 80369-3: 2016 Small-bore connectors for liquids and gases in healthcare applications- Part3: Connectors for enteral applications.
g. Printing Firmness Test in accordance with ASTM D3359-09 Standard Test Methods for Measuring Adhesion by Tape Test.
h. Priming Volume Test
i. Flow Rate Test using Enfamil solution
j. Radiopaque Capacity Test
k. Connector Incapability test with specific connectors which defined in ISO 80369-1: 2010 Section 5.1 & Annex B.

The following performance testing of the Enteral Feeding Extension Sets (EFES) was conducted.

a. Connector Compatibility Test in accordance with section 4.1.2 of EN1615: 2000 Enteral feeding catheters and enteral giving sets for single use and their connectors-Design and testing and ANSI/AAMI ID54: 1996/(R) 2012 Enteral feeding set adapters and connectors.
b. Connector Performance test in accordance with ISO 80369-3: 2016 Small-bore connectors for liquids and gases in healthcare applications- Part3: Connectors for enteral applications.
c. Tensile Property Test of tubing in accordance with section 4.1.1 of EN1615: 2000 Enteral feeding catheters and enteral giving sets for single use and their connectors-Design and testing.
d. Tensile Property Test of bonding between connectors and tubing in accordance with section 4.1.1 of EN1615: 2000 Enteral feeding catheters and enteral giving sets for single use and their connectors-Design and testing.
e. Liquid Leakage Test in accordance with section 4.1.3 & 4.3.2 of EN1615: 2000 Enteral feeding catheters and enteral giving sets for single use and their connectors-Design and testing.
f. Tensile Property test of Assembled connection of connectors in accordance with section 4.3.1 of EN1615: 2000 Enteral feeding catheters and enteral giving sets for single use and their connectors-Design and testing.
g. Priming Volume Test
h. Flow Rate Test using Enfamil solution
i. Connector Incapability test with specific connectors which defined in ISO 80369-1: 2010 Section 5.1 & Annex B.

Biocompatibility
The biocompatibility evaluation for the Enteral Feeding Tube and Enteral Feeding Extension Set was conducted in accordance with the FDA Draft Guidance on the Use of International Standard ISO 10993-1, “Biological Evaluation of Medical Devices Part 1: Evaluation and Testing”.

The VR Medical Enteral Feeding Tubes are a

- Surface Contacting, mucosal membrane, prolonged duration (> 24 hours, < 30 days)

The Enteral Feeding Extension Set (EFES) are

- Externally Communicating, Tissue, Limited duration (< 24 hours)

ISO 10993-1 would require cytotoxicity, sensitization, and irritation, Acute systemic and Sub-acute toxicity, Implantation (14 day) and Pyrogenicity.

Substantial Equivalence Conclusion -
Based on the results of the comparison of intended use and technological characteristics, the VR Medical Feeding Tube and Feeding Extension Set are substantially equivalent to their respective predicate devices.