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 1, 2016

Covidien
Sona Manickam
Senior Regulatory Affairs Specialist
15 Hampshire Street
Mansfield, MA 02048

Re: K161963
Trade/Device Name: Monoject™ Enteral Syringe with ENFit Connector
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: II
Product Code: PNR
Dated: July 15, 2016
Received: July 18, 2016

Dear Sona Manickam:

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,

For Division

Douglas Silverstein -S
2016.09.01 12:36:01
-04'00'

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

1.0 Indications for Use Statement

Indications for Use

510(k) Number (if known): K161963

Device Name:

Monoject™ Enteral Syringe with ENFit Connector

The Monoject™ Enteral Syringe with ENFit Connector is indicated for use as a dispenser, a measuring device, and a fluid transfer device. It is used to deliver fluids, either orally or enterally, into the gastrointestinal system of a patient. The oral/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.

Prescription Use ____X_____ (Part 21 CFR 801 Subpart D)

AND/OR

Over the Counter Use_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

2.0 510(k) Summary

Monoject™ Enteral Syringe with ENFit Connector

In accordance with section 513(i) of the SMDA and as defined in 21CFR Part 807.92 this summary is submitted by:

Covidien
15 Hampshire Street
Mansfield, MA 02048
Date Prepared: August 15, 2016

a. Contact Person

Sona Manickam
Sr. Regulatory Affairs Specialist
Covidien
Telephone: (508) 261-8147

b. Name of Medical Device

Common Name: Enteral Syringes with Enteral Specific Connectors

U.S. FDA Classification Product Code: PNR

U.S. Regulation Description: Gastrointestinal tube and accessories, 21 CFR 876.5980

Proprietary / Trade Name: Monoject™ Enteral Syringe with ENFit Connector

c. Identification of Legally Marketed Device(s)

K160419 - Monoject™ Enteral Feeding Syringe with ENFit Connector (sizes 6-60mL)
K161045 - Monoject™ Enteral Feeding Syringe with ENFit Connector (sizes 1 & 3mL)
K161039 – 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 6mL)

d. Device Brief Description

The Monoject™ Enteral Syringes with ENFit Connector are provided in sizes of 1mL to 60mL, sterile or non-sterile. The device (sizes 6mL to 60mL) incorporates a female ENFit connector for connection to an enteral access device with male ENFit connector. The device specific for low dose applications (sizes 1mL & 3mL) incorporates a female ENFit Syringe tip with an internal tip lumen for connection to an enteral access device with male ENFit connector.

e. Indications for Use

The Monoject™ Enteral Syringe with ENFit Connector is indicated for use as a dispenser, a measuring device, and a fluid transfer device. It is used to deliver fluids, either orally or enterally, into the gastrointestinal system of a patient. The oral/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.

f. Product Comparison Summary

The proposed and the predicate syringes have the same intended use, the same function, and the same general characteristics. The primary difference between the predicate and the proposed Monoject™ Enteral Syringe with ENFit Connector is the intended route of administration and the packaging configuration. The proposed devices are identical in dimensions, materials, and function as the predicate Monoject™ Enteral Feeding Syringe with ENFit Connector **(K160419 & K161045)**.

g. Nonclinical testing

- Biocompatibility testing has demonstrated the biological safety of the proposed devices which may indirectly contact the patients

- Stability testing evaluated the properties of the enteral syringes after accelerated aging in support of the labeling.

- Dimensional analysis of the ENFit and Low Dose Tip ENFit connector was conducted for critical dimensions, in accordance with AAMI /CN3 (PS):2014, Small-bore connectors for liquids and gases in healthcare applications – Part 3: Connectors for enteral applications. The analysis demonstrates the proposed devices conform to the criteria in Table B.2 of AAMI /CN3 (PS):2014.

- Additional Testing performed on the Monoject™ Enteral Syringes with ENFit and Low Dose Tip ENFit Connector included the items listed below, in accordance with AAMI /CN3 (PS):2014, Small-bore connectors for liquids and gases in healthcare applications – Part 3: Connectors for enteral applications, using the test methods provided in ISO 80369-20, Small-bore connectors for liquids and gases in healthcare applications – Part 20: Common test methods. The testing demonstrates the proposed devices conform to the requirements of ISO 80369-20.

Individual Test Defined in AAMI /CN3 (PS):2014	Requirement Defined in AAMI /CN3 (PS):2014	Test Method Defined in ISO 80369-20
Fluid Leakage	Clause 6.2	Annex C
Stress Cracking	Clause 6.3	Annex E
Resistance to separation from axial load	Clause 6.4	Annex F
Resistance to separation from unscrewing	Clause 6.5	Annex G
Resistance to overriding	Clause 6.6	Annex H
Disconnection by unscrewing	Clause 6.7	Annex I

- Verification of the Enteral Syringes to demonstrate the direct oral administration Dosing Accuracy and Low Dose Syringe design Dosing Accuracy.

- The risk associated with the misconnection of the ENFit tip and Low Dose Tip ENFit connector has been assessed.

- ENFit Syringe Tip and Low dose Tip Usability Testing.

h. Clinical testing

Clinical evaluations were not relied upon for evidence of safety of effectiveness, or for a determination of substantial equivalence.

i. Conclusions

The information provided within this pre-market notification demonstrates that the Monoject™ Enteral Syringe with ENFit Connector has no difference that would affect the safety or effectiveness of the devices as compared to the predicate devices and provides reasonable assurance of the safety and effectiveness of the device to demonstrate substantial equivalency.

End of Summary