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

May 12, 2016

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

Re: K160419
Trade/Device Name: Monoject™ Enteral Feeding Syringe with ENFit Connector
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal Tubes and Accessories
Regulatory Class: II
Product Code: PNR
Dated: February 12, 2016
Received: February 16, 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 yours,

Herbert P. Lerner -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

1.0 Indications for Use Statement

Indications for Use

510(k) Number (if known): K160419

Device Name:

Monoject™ Enteral Feeding Syringe with ENFit Connector

The Monoject™ Enteral Feeding 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 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.

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 Feeding 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: May 5, 2016

a. Contact Person

Sona Manickam
Sr. Regulatory Affairs Specialist
Covidien
Telephone: (508) 261-8147
Fax: (508) 261-8461

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 Feeding Syringe with ENFit Connector

c. Identification of Legally Marketed Device(s)

K142128 – Kangaroo™ Enteral Feeding Syringe with ENFit Connector
K152857 – NeoMed NeoConnect™ Enteral Syringes with ENFit Connector and compatible NeoSecure™ Tip Caps

d. Device Brief Description

The Monoject™ Enteral Feeding Syringe with ENFit Connector is a disposable enteral feeding syringe provided in a variety of sizes from 6mL to 60mL. The device incorporates a female ENFit connector for connection to an enteral access device with male ENFit connector.

e. Indications for Use

The Monoject™ Enteral Feeding 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 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.

f. Product Comparison Summary

The proposed and predicate enteral feeding syringes are intended for patients who require enteral nutrition due to illness or injury which prevents normal chewing and swallowing. These products are enteral syringes that have the same intended use, the same function, and the same general characteristics.
The design and materials of the proposed devices are identical to the predicate Kangaroo™ Enteral Feeding Syringe with ENFit Connector (K142128). The only difference between the cleared K142128 predicate and the proposed device is the expansion of the cleared indication to include enteral delivery of fluids in addition to the already cleared indication of delivery of enteral nutrition.

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 feeding syringes after accelerated aging in support of the labeling.

- Dimensional analysis was conducted for critical dimensions of the Monoject Enteral Feeding Syringes with ENFit connector and the accessories, in accordance with ISO 80369-3, Small-bore connectors for liquids and gases in healthcare applications – Part 3: Connectors for enteral applications. The testing demonstrates the proposed devices conform to the criteria in Table B.2 of AAMI /CN3 (PS):2014.

- Testing performed on the Monoject™ Enteral Feeding Syringes with ENFit Connectors 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 AAMI /CN3 (PS):2014.

Individual Test Defined in ISO 80369-3	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

- The risk associated the misconnection of the ENFit connector has been assessed at length and captured in the following documents..

    - o PG Lock Misconnection Data with FMEA 2014-01-9
    - o 3595-0501-04 Enteral Connector Misconnection Assessment
    - o Enteral Connection Risk Management Report Rev 2.0
    - o PG Lock Misconnection Risk Assessment Report 041513

- Usability and human factors testing was conducted as part of the design of the ENFit connector.

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 Feeding Syringe with ENFit Connector has no difference that would affect the safety or effectiveness of the devices as compared to the predicate device and provide reasonable assurance of the safety and effectiveness of the device to demonstrate substantial equivalency.

End of Summary