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

November 29, 2016

Medline Industries, Inc.
Stephanie Blair
Regulatory Affairs Manager
One Medline Place
Mundelein, IL 60060

Re: K160642
Trade/Device Name: Medline ENFit Syringe
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: II
Product Code: PIF
Dated: November 29, 2016
Received: November 29, 2016

Dear Stephanie Blair:

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,

Benjamin R. Fisher -S

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)*
K160642

Device Name
Medline ENFit Syringe

Indications for Use *(Describe)*
The Medline ENFit Syringe is intended to be used in clinical or home care settings by users ranging from clinicians to laypersons (under the supervision of a clinician) to measure and administer enteral nutrition.

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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SECTION 5
510(k) SUMMARY

Summary Preparation Date
November 17th, 2016

Submitter / 510(k) Sponsor
Medline Industries, Inc.
One Medline Place
Mundelein, IL 60060
Registration Number: 1417592

Submission Correspondent
Stephanie Augsburg
Manager, Regulatory Affairs
Phone: 847-643-3690
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Type of 510(k) Submission
Traditional

Device Name / Classification
Proprietary Name: Medline ENFit Syringe
Common Name: Gastrointestinal tubes with enteral specific connectors
Regulation Name: Gastrointestinal Tube and Accessories
Product Code: PIF
Regulatory Class: II
Classification Panel: Gastroenterology / Urology

Predicate Devices
A. **K142128** - Covidien Kangaroo™ Enteral Feeding Syringes with ENFit connector
B. **K152857 -** NeoMed NeoConnect™ Enteral Syringes with ENFit™ Connector and compatible NeoSecure™ Tip Caps

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Device Description

The Medline ENFit Syringe is a standard piston syringe which incorporates an ENFit connector. The device incorporates a female ENFit connector for connection to an enteral access device. The Medline ENFit Syringe is designed to mate with a range of enteral feeding extension sets. The 3-piece design syringe consists of a polypropylene barrel and plunger rod and a polyisoprene stopper. The Medline ENFit syringe comes with a cap as other predicate devices seen below. The Medline ENFit syringe will be sold as non-sterile. The performance of the Medline ENFit Syringe is equivalent to the predicate devices.

Indications for Use

The Medline ENFit Syringe is intended to be used in clinical or home care settings by users ranging from clinicians to laypersons (under the supervision of a clinician) to measure and administer enteral nutrition.

Summary of Technological Characteristics

Medline ENFit Syringes are made of polypropylene and are non-sterile, single-use devices. In addition, the ENFit Syringe is made of semi-rigid materials to reduce the likelihood of forced fits between flexible connectors that are not intended to connect with each other, as recommended in FDA Final Guidance for Industry: Safety Considerations to Mitigate the Risks of Misconnections with Small-bore Connectors Intended for Enteral Applications (February 11, 2015).

In addition, Medline ENFit Syringes are similar in design, intended use, function and internal and external characteristics to the predicate device cleared under K142128, Covidien Kangaroo™ Enteral Feeding Syringes with ENFit connector, as well as K152857, NeoMed NeoConnect™ Enteral Syringes with ENFit™ Connector and compatible NeoSecure™ Tip Caps.

Device Characteristic	Proposed Device	Predicate Device	Predicate Device	Comparison Analysis
Product Name	Medline ENFit Syringe	NeoMed NeoConnect™ Enteral Syringes with ENFit™ Connector and compatible tip caps	Covidien Kangaroo™ Enteral Feeding Syringes with ENFit	Similar
Product Owner	Medline Industries, Inc.	NeoMed	Covidien	Different
Product Code	PIF	PIF	PIF	Same
Intended Use	The Medline ENFit Syringe is intended to be used in clinical or home care	NeoMed NeoConnect™ Enteral Syringes with ENFit™ Connector and	The Kangaroo™ Enteral Feeding Syringe with ENFit Connector delivers	Same

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	settings by users ranging from clinicians to laypersons (under the supervision of a clinician) to measure and administer enteral nutrition.	compatible tip caps are indicated for use as a dispenser, a measuring device and a fluid transfer device intended to be used in clinical or home care settings by users ranging from clinicians to laypersons (under the supervision of a clinician) in all age groups.	nutritional formula to the gastrointestinal system of a patient who is physically unable to eat and swallow. The feeding syringes are intended to be used in clinical or home care settings by users ranging from laypersons to clinicians (under the supervision of a clinician), to administer enteral nutrition. The syringe is intended for all age groups.	
Regulation Number	21 CFR 876.5980	21 CFR 876.5980	21 CFR 876.5980	Same
Design Features	3 piece design syringe with cap	3 piece design syringe with or without cap	3 piece design syringe	Similar
Design Configurations	60 ml non-sterile	0.5 – 100 mL	Not specified in 510(k) summary	Similar
Materials	Polypropylene translucent barrel and plunger rod	Translucent barrel	Not specified in 510(k) summary	Similar
Prescription vs. OTC	Prescription	Prescription	Prescription	Same
Contact Durations	≤ 24 hours	≤ 24 hours	≤ 24 hours	Same
Sterile vs. Non-Sterile	Non-Sterile	Non-Sterile and Sterile	Not specified in 510(k) summary	Similar
Single Use vs. Reusable	Single Use	Single Use	Single Use	Same
Disposable vs. Non-Disposable	Disposable	Disposable	Disposable	Same
Syringe Tip (ISO 80369-3 ENFit) female connector	Liquid Leakage Testing Stress Cracking Resistance to separation from axial load Resistance to separation from unscrewing Resistance to overriding	Liquid Leakage Testing Stress Cracking Resistance to separation from axial load Resistance to separation from unscrewing Resistance to overriding	Fluid Leakage Stress Cracking Resistance to separation from axial load Resistance to separation from unscrewing Resistance to overriding	Same

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	Disconnection by unscrewing	Disconnection by unscrewing	Disconnection by unscrewing	
ISO 7886 Syringe Testing	Tolerance on Graduated Capacity Graduated Scale: Scale, Numbering of Scale, Overall Length of Scale, Position of Scale Barrel Finger Grips Piston / Plunger Assembly Design Fit of Piston in Barrel Fiducial line Dead Space Freedom from Air / Liquid Leakage	Capacity Tolerance Graduated Scale Piston Fit in Barrel Air and Liquid Leakage Testing	Not specified in 510(k) summary	Similar

Summary of Non-Clinical Testing

Non-clinical verification of Medline ENFit Syringes has been conducted to evaluate the safety, performance and functionality of Medline ENFit Syringes. The results of these tests have demonstrated the overall safety of the proposed device and ultimately support a substantial equivalence determination. Specifically, the proposed device has been evaluated through the following tests:

- Enteral Connector Misconnection Assessment Study
- Human Factors Validation Study: Enteral Connectors Final Report
- PG-Lock Misconnection Data with Failure Modes and Effects Analysis (FMEA)
- Internal Risk Analysis
- Bioburden Testing
- Metrology Testing
- Stability (Shelf-Life) Testing
- Biocompatibility Testing:
  - Cytotoxicity – MEM elution per ISO 10993-5
  - Irritation – Intracutaneous reactivity per ISO 10993-10
  - Delayed-Type Hypersensitivity (Sensitization) – Guinea Pig Maximization Test per ISO 10993-10

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Summary of Non-Clinical Testing (continued)

- ISO 80369-20 Testing:
  - Positive Pressure Liquid Leakage
  - Stress Cracking
  - Resistance to Separation from Axial Load
  - Resistance to Separation from Unscrewing
  - Resistance to Overriding
  - Disconnection by Unscrewing
- ISO 7886-1 Testing:
  - Tolerance on Graduated Capacity
  - Graduated Scale: Scale, Numbering of Scale, Overall Length of Scale, Position of Scale
  - Barrel Finger Grips
  - Piston / Plunger Assembly Design
  - Fit of Piston in Barrel
  - Fiducial line Dead Space
  - Freedom from Air / Liquid Leakage

Summary of Clinical Testing

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

Conclusion

In accordance with 21 CFR Part 807, and based on the information provided in this premarket notification, Medline Industries, Inc. concludes that the Medline ENFit Syringes are substantially equivalent to the predicate devices, the Covidien Kangaroo™ Enteral Feeding Syringes with ENFit connector (K142128) and the NeoMed NeoConnect™ Enteral Syringes with ENFit™ Connector and compatible NeoSecure™ Tip Caps (K152857), as described herein.

Submitted by: Stephanie Augsburg
Prepared by: Jessica Rivera-Montejo