December 7, 2020

Medline Industries, Inc.
Dinah Rincones
Sr. Regulatory Affairs Specialist
Three Lakes Drive
Northfield, Illinois 60093

Re: K202285
Trade/Device Name: Medline ENfit OTC Feeding Syringe
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: Class II
Product Code: PNR

Dear Dinah Rincones:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated October 9, 2020. Specifically, FDA is updating this SE Letter due to an inadvertent inclusion of proprietary information (contract manufacturer) as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Shanil Haugen, Ph.D., OHT3: Office of GastroRenal, ObGyn, General Hospital and Urology Devices Office, (301) 796-0301, Shanil.Haugen@fda.hhs.gov.

Sincerely,

Shanil P. Haugen -S

Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal, Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn, General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

October 9, 2020

Medline Industries, Inc.
Dinah Rincones
Sr. Regulatory Affairs Specialist
Three Lakes Drive
Northfield, IL 60093

Re: K202285
Trade/Device Name: Medline ENfit OTC Feeding Syringe
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: PNR
Dated: August 7, 2020
Received: August 12, 2020

Dear Dinah Rincones:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jitendra V. Virani -S

For Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal, Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn, General Hospital and Urology Devices
Office of Product Evaluation and Quality
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)*
K202285

Device Name
Medline ENFit OTC Feeding Syringe

Indications for Use *(Describe)*
The Medline ENFit OTC Feeding Syringe is intended for Over-The-Counter use 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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SECTION 5
510(k) SUMMARY

Submitter
Dinah Rincones
Medline Industries, Inc.
Three Lakes Drive
Northfield, IL 60093
Phone: 847-949-2687
Fax: 224-931-1271
Email: DRincones@medline.com

Device Information

Device Common Name:	Enteral Syringes with Enteral Specific Connectors
Trade Name:	Medline ENFit OTC Feeding Syringe
Regulation Name:	Gastrointestinal Tube and Accessories
Regulation Number:	21 CFR §876.5980
Class:	Class II
Review Panel:	Gastroenterology/Urology
Product Code:	PNR

Predicate Device Information
The proposed predicate device is Medline ENFit Syringe cleared under 510(k) number K160642 on November 29, 2016.

Modification to the Predicate Device
The intent of this traditional 510(k) is to expand the intended use of the previously cleared Medline ENFit Syringe (K160642) in order to include over-the-counter (OTC) use. The device that is the subject of this submission is the same as the legally marketed device Medline ENFit Syringe (K160642), but rather than being intended for prescription use only, is intended for over-the-counter use. According to the FDA guidance document, "Deciding When to Submit a 510(k) for a Change to an Existing Device," a change from prescription use to OTC use requires the development of adequate directions for use so that the lay user is able to utilize that same device safely and effectively. Therefore, changing a device labeled for prescription use only to a device that is labeled for OTC use requires a submission of a new 510(k). For this reason, the Medline ENFit Syringe (K160642) will be utilized as the primary predicate device in this submission.

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Device Description

The device that is the subject of this submission is the same device as the Medline ENFit Syringe cleared under K160642, but rather than being intended for prescription use only, is instead intended for over-the-counter use. The Medline ENFit OTC Feeding Syringe (the subject device) is a standard piston syringe which incorporates a female ENFit connector designed to interact with enteral access devices (i.e. feeding tubes) and ENFit compatible enteral feeding extension sets. The design consists of a polypropylene barrel and plunger rod, a polyisoprene plunger seal or stopper, an ISO 80369-3 compliant female ENFit connector, and a threaded cap. The Medline ENFit OTC Feeding Syringe is available in one size (60mL) and will be sold as a single use, non-sterile device.

Indications for Use

The Medline ENFit OTC Feeding Syringe is intended for Over-The-Counter use to measure and administer enteral nutrition.

Summary of Technological Characteristics

Table 1: Comparison of Proposed and Predicate Devices

Device Characteristic	Proposed Device	Predicate Device (K160642)	Comparison Analysis
Product Name	Medline ENFit OTC Feeding Syringe	Medline ENFit Syringe	**N/A**
Regulation Name/Number	21 CFR §876.5980 - Gastrointestinal tube and accessories	21 CFR §876.5980 - Gastrointestinal tube and accessories	**Same**
Product Code	PNR	PIF	**Different** *Note: Product Code PNR did not exist at the time of K160642 submission. Currently there is a specific product code for this type of devices (PNR).*
Intended Use	Intended to measure and administer enteral nutrition.	Intended to measure and administer enteral nutrition.	**Same**
Indications for Use	The Medline ENFit OTC Feeding Syringe is intended for Over-The-Counter use to measure and administer enteral nutrition.	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.	**Different**

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Device Characteristic	Proposed Device	Predicate Device (K160642)	Comparison Analysis
Patient Population	Adults and pediatrics (but not neonates).	Adults and pediatrics (but not neonates).	**Same**
Prescription vs. OTC	OTC	Prescription	**Different** Note: The agency has cleared ENFit OTC Feeding Syringes (K183540)
Use Environment and Users	Clinical or home care settings by users ranging from clinicians to laypersons	Clinical or home care settings by users ranging from clinicians to laypersons (under the supervision of a clinician).	**Similar**
Design Features	3 piece design syringe with cap. Components: • Syringe Barrel • Syringe Plunger • Syringe Plunger Seal • Syringe Threaded Cap	3 piece design syringe with cap. Components: • Syringe Barrel • Syringe Plunger • Syringe Plunger Seal • Syringe Threaded Cap	**Same**
Design Configurations	60 ml non-sterile	60 ml non-sterile	**Same**
Materials	Syringe Barrel: Polypropylene Syringe Plunger: Polypropylene Syringe Plunger Seal: Polyisoprene Syringe Threaded Cap: Polypropylene Packaging Material: Low Density Polyethylene (LDPE).	Syringe Barrel: Polypropylene Syringe Plunger: Polypropylene Syringe Plunger Seal: Polyisoprene Syringe Threaded Cap: Polypropylene Packaging Material: Low Density Polyethylene (LDPE).	**Similar** *Note: The type of material per component is the same; however, the raw material supplier is different.*
Contact Duration	≤ 24 hours	≤ 24 hours	**Same**
Sterile vs. Non-Sterile	Non-Sterile	Non-Sterile	**Same**

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Device Characteristic	Proposed Device	Predicate Device (K160642)	Comparison Analysis
Disposable vs. Non-Disposable	Disposable	Disposable	**Same**
Single Use vs. Reusable	Single Use	Single Use	**Same**
Sterile vs. Non-Sterile	Non-sterile	Non-sterile	**Same**
Single Use vs. Reusable	Single use	Single use	**Same**
Shelf Life	3 years	3 years	**Same**

Summary of Testing and Supporting Information

Testing was conducted to demonstrate substantial equivalence of Medline ENFit OTC Feeding Syringe to the predicate, Medline ENFit Syringe cleared under 510(k) number K160642. A summary of testing is presented below with more information provided in the applicable sections.

Biocompatibility Testing

The biological evaluation for the Medline ENFit OTC Feeding Syringe was conducted in accordance with FDA guidance document, "*Use of International Standard ISO 10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing*" and ISO 10993-1 *Biological Evaluation of the Medical Devices – Part 1: Evaluation of Testing within a Risk Management Process."*

Testing performed:

1. MEM Elution Cytotoxicity Test per ISO 10993-5: 2009 "Biological Evaluation of Medical Devices, Part 5: Tests for *in vitro* Cytotoxicity."
1. Intracutaneous Reactivity Test per ISO 10993-10: 2010: "Biological Evaluation of Medical Devices- Part 10: Tests for Irritation and Skin Sensitization."
2. Guinea Pig Maximization Sensitization Test per ISO 10993-10: 2010: "Biological Evaluation of Medical Devices- Part 10: Tests for Irritation and Skin Sensitization."

Performance Testing (Bench)

The following performance testing was conducted on Medline ENFit OTC Feeding Syringe:

ISO 7886-1 Sterile hypodermic syringes for single use - Part 1: Syringes for manual use.

- Tolerance on Graduated Capacity per Section 9.
- Graduated Scale: Scale per Section 10.1.

- Graduated Scale: Numbering of Scale per Section 10.2.
- Overall Length of the Scale per Section 10.2.
- Position of the Scale per Section 10.4.
- Burrell Finger Grips per Section 11.2.
- Piston/Plunger Assembly Design per Section 12.1.
- Fit of Piston in Barrel per Section 12.2.
- Fiducial Line per Section 12.3.
- Dead Space per Section 14.1.
- Freedom from Liquid Leakage per Section 14.2.
  Freedom from Air Leakage per Section 14.2.

Connectors for enteral applications.

- Positive Pressure Liquid Leakage per Section 6.1.3.
- Stress Cracking per Section 6.2.
- Resistance to Separation from Axial Load per Section 6.3.
- Resistance to Separation from Unscrewing per Section 6.4.
- Resistance to Overriding per Section 6.5.
  Disconnection by Unscrewing per Section 6.6.

Force to Insert Plunger.

Maximum Force (N) required to surpass the interference ring of the barrel: Met acceptance criteria.

Metrology per ISO 80369-3 – Dimensions of Female ENFit Connector.

All dimensions for the female connectors meet the specifications and tolerance listed in ISO 80369-3.

Performance Testing (Animal)

This section does not apply. No animal testing was performed.

Performance Testing (Clinical)

This section does not apply. No clinical testing was performed.

Phthalates Testing

Phthalates testing supports that the Medline ENFit OTC Feeding Syringe is not made with DEHP or BPA.

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Northfield, IL 60093

Stability (Shelf-Life) Testing

Stability testing has been performed on the final finished product to validate a shelf life of up to three (3) years based on real time and accelerated aging conditions of 25°C/60% relative humidity (RH) and 65°C dry heat, respectively.

Usability Studies

Usability studies have been executed in order to validate the adequacy of the printed instructions for how to properly fill and administer the Medline ENFit OTC Feeding Syringe contents by the layperson.

Risk Analysis

A complete Use Risk Assessment was performed for the Medline ENFit OTC Feeding Syringe.

Conclusion

In accordance with 21 CFR Part 807, and based on the information provided in this premarket notification, Medline Industries, Inc. concludes that the proposed Medline ENFit OTC Feeding Syringe is as safe and as effective for its intended use as the predicate device Medline ENFit Syringe (K160642).