December 4, 2019

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

Re: K191759
Trade/Device Name: Medline Quick Switch Valve with ENFit Connector
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: PIF
Dated: November 5, 2019
Received: November 6, 2019

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,

for
Shani P. Haugen, Ph.D.
Acting 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)*

K191759

Device Name
Medline Quick Switch Valve with ENFit Connector

Indications for Use *(Describe)*

The Medline Quick Switch Valve with ENFit Connector is a multi-port connector/valve closed system indicated for controlling fluid flow (nutrition, medication and water) between ENFit compatible devices, while reducing the frequency of disconnections between the associated ENFit devices. The Medline Quick Switch Valve with ENFit Connector can be used in pediatric (infants over 10kg, children, and adolescents) and adult patients, for up to 30 days.

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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Medline Industries, Inc.
Three Lakes Drive
Northfield, IL 60093

K191759
510(k) SUMMARY
[AS REQUIRED BY 21CFR807.92(c)]

Submitter / 510(k) Sponsor
Medline Industries, Inc.
Three Lakes Drive
Northfield, IL 60093
Registration Number: 1417592

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

Summary Preparation Date
November 26th, 2019

Type of 510(k) Submission
Traditional

Device Information

Type of 510(k) Submission:	Traditional
Device Common Name:	Gastrointestinal tube valve
Trade Name:	Medline Quick Switch Valve with ENFit Connector
Regulation Name:	Gastrointestinal tube and accessories
Regulation Number:	21 CFR §876.5980
Class:	Class II
Review Panel:	Gastroenterology/Urology
Product Code:	PIF (Gastrointestinal tubes with enteral specific connectors)

Predicate Device
ICU Medical Lopez Valve
K915171

Reference Device

Medline ENFit Syringe
K160642

Dale Medical Products, Inc. Dale ACE Connector (Access Controller for Enteral) K082241

Medline ENFit Connectors
K151628

Medline Enteral Feeding Sets
K150286

Device Description

The Medline Quick Switch Valve with ENFit Connector is a three-way stopcock valve intended to contro
l
fluid flow between ENFit enteral devices (i.e., Gastrostomy tubes, enteral syringes, extension sets, feedin
g sets) used for different enteral functions (i.e., liquid nutrition, water, or medication administration), reducing the frequency of disconnections between the associated enteral devices.

TABLE:1 Quick Switch Valve with ENFit Connector Offerings

Item	Description
ENFit9000S	Medline Quick Switch Valve with ENFit Connector sterile
ENFit9000NS	Medline Quick Switch Valve with ENFit Connector non-sterile

Indications for Use

The Medline Quick Switch Valve with ENFit Connector is a multi-port connector/valve closed system indicated for controlling fluid flow (nutrition, medication and water) between ENFit compatible devices, while reducing the frequency of disconnections between the associated ENFit devices. The Medline Quick Switch Valve with ENFit Connector can be used in pediatric (infants over 10kg, children, and adolescents) and adult patients, for up to 30 days.

Summary of Technological Characteristics

The Medline Quick Switch Valve with ENFit Connector is similar in design and technological characteristics to the predicate device cleared under K915171, ICU Medical Lopez Valve. Variations from the predicate device design are nonsignificant. The table below shows a side-by-side comparison of the key attributes associated with the proposed device and the predicate device.

TABLE 2: Comparison of the Proposed Device with the Predicate

Device Characteristic	Proposed Device	Predicate Device (K915171)	Comparison Analysis
Product Name	Medline Quick Switch Valve with ENFit Connector	ICU Medical Lopez Valve	**N/A**
Intended Use	Intended for use in providing access to enteral systems without opening or breaking the fluid delivery lines.	Intended for use in providing access to enteral systems without opening or breaking the fluid delivery lines.	**Same**
Indications for Use	The Medline Quick Switch Valve with ENFit Connector is a multi-port connector/valve closed system indicated for controlling fluid flow (nutrition, medication and water) between ENFit compatible devices, while reducing the frequency of disconnections between the associated ENFit devices.	*Note: The predicate's device 510(k) Summary or Indications for Use Statement are not publicly available.*	N/A

Device Characteristic	Proposed Device	Predicate Device (K915171)	Comparison Analysis
Regulation Name/Number	21 CFR §876.5980 - Gastrointestinal tube and accessories	21 CFR §876.5980 - Gastrointestinal tube and accessories	**Same**
Product Code	PIF	KNT	**Different** *Note: Currently this device's design has been updated to include ENFit connector. Refer to its promotional material in Appendix C.*
Materials	Valve Body: Polycarbonate Valve Knob: High Density Polyethylene Valve Plate: High Density Polyethylene Female/Mate ENFit Connector: Polycarbonate Cap: Polycarbonate Tether: PVC	Valve Body: Polycarbonate. Valve Core: Low linear density polyethylene. Cap: Polyethylene.	**Similar**
Design Features	Three-way stopcock. One female ENFit end/connector.	Three-way stopcock. One female ENFit end/connector.	**Similar**

Device Characteristic	Proposed Device	Predicate Device (K915171)	Comparison Analysis
	Two male ENFit ends/connectors with tethered caps. On-Off 360° rotation handle.	One male ENFit end/connector w/o cap. One male ENFit end/connector with tethered cap. On-Off 360° rotation handle.	
Product Configurations	Sterile and non-sterile configurations	Sterile and non-sterile configurations	**Same**
Packaging	Individually packaged in a soft poly film pouch with Tyvek lid.	Individually packaged in a soft poly film pouch with Tyvek lid.	**Same**
Performance Characteristics	The following performance characteristics are equivalent to the predicate device: • Flow rate • ENFit connectors compliant with ISO 80369-3	The following performance characteristics are equivalent to the predicate device: • Flow rate • ENFit connectors compliant with ISO 80369-3	**Same**
Prescription vs. OTC	Prescription only	Prescription only	**Same**
Duration of Use	**< 30 days** Change per institutional protocol.	**Acute care: < 7 days.** **Other care settings: May be used longer.**	**Different**

Device Characteristic	Proposed Device	Predicate Device (K915171)	Comparison Analysis
	Not recommended for use over 30 days.	*Note: Refer to the predicates promotional material in Appendix C.*	
Sterile vs. Non-Sterile	Sterile and non-sterile configurations	Sterile and non-sterile configurations	**Same**
Single Use vs. Reusable	Single use	Single use	**Same**
Shelf Life	Yes: 3 years	Not stated	**N/A**

Summary of Testing and Supporting Information

Non-clinical verification of The Medline Quick Switch Valve with ENFit Connector has been conducted to evaluate its safety, performance and functionality. The results of these tests have demonstrated the overall safety of the proposed device and ultimately support a substantial equivalence determination of Medline Quick Switch Valve with ENFit Connector to the predicate, ICU Medical Lopez Valve (K915171). A summary of testing is presented below.

Biocompatibility Testing

The biological evaluation for the Medline Quick Switch Valve with ENFit Connector 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."*

Based on the indications for use, the proposed device has been classified as follows:

Per nature of body contact

Surface device, indirectly contacting mucosal membrane (gastrointestinal).

Per contact duration

Prolonged (>24 hours to 30 days)

Based on the proposed device indications for use, its categorization, and its material composition the following biocompatibility tests were performed on the final finished sterilized device:

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

The biocompatibility test results indicate that the Medline Quick Switch Valve with ENFit Connector is considered to be non-cytotoxic, non-sensitizing, and a non-irritant. Collectively, the test results indicate that the product meets the biocompatibility requirements and is considered safe for its intended use.

Phthalates Testing
Phthalates testing supports that the Medline Quick Switch Valve with ENFit Connector is not made with DEHP or BPA.

Bioburden Testing
The environmental controls and bioburden monitoring supports safe bioburden levels for the indications for use.

Performance Testing (Bench)
To evaluate the performance of the proposed device, the Medline Quick Switch Valve with ENFit Connector was subjected to:

- Metrology per ISO 80369-3
- Positive Pressure Liquid Leakage per ISO 80369-3 § 6.1.3
- Stress Cracking per ISO 80369-3 § 6.2
- Resistance to Separation from Axial Load per ISO 80369-3 § 6.3
- Resistance to Separation from Unscrewing per ISO 80369-3 § 6.4
- Resistance to Overriding per ISO 80369-3 § 6.5
- Disconnection by Unscrewing per ISO 80369-3 § 6.6
- Flow Rate*
- Tensile testing
- Torque testing

**Predicate device included for comparison in testing.*

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.

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Conclusion

In accordance with 21 CFR Part 807, and based on a comparison of 'Indications for Use,' technological characteristics and performance data, Medline Industries, Inc. concludes that the proposed Medline Quick Switch Valve with ENFit Connector is substantially equivalent to the predicate device, ICU Medical Lopez Valve (K915171).