May 4, 2019

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

Re: K183577
Trade/Device Name: Medline Quick-Clear Wand
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: II
Product Code: KNT
Dated: March 29, 2019
Received: April 1, 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shanil P. Haugen, Ph.D.
Acting, Assistant Division 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)*
K183577

Device Name
Medline Quick-Clear Wand

Indications for Use *(Describe)*
Medline Quick-Clear Wand is intended to be used by health care providers to restore and maintain patency of gastrostomy tubes (G-Tubes), jejunostomy tubes (J-Tubes), and percutaneous endoscopic (PEG) tubes that may be used in infant patients over 10kg, children, adolescents, and adults.

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."

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

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
May 1st, 2019

Type of 510(k) Submission
Traditional

Device Name / Classification

Device Common Name:	Feeding tube de-clogger
Trade Name:	Medline Quick-Clear Wand
Regulation Name:	Gastrointestinal Tube and Accessories
Regulation Number:	21 CFR §876.5980
Class:	Class II
Panel:	Gastroenterology/Urology
Product Code:	KNT

Predicate Device
Tube DeClogger
K905164

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Device Description

The Medline Quick-Clear Wand is a single use device intended for use in clearing occlusions/clogs from gastrostomy tubes (G-Tubes) and Percutaneous Endoscopic Gastrostomy tubes (PEG tubes) – tubes that are placed through the abdomen wall and rest in the stomach of the patient, and jejunostomy tubes (J-Tubes) - tubes that are placed through the abdomen wall and rest in the jejunum of the patient. The proposed device is manually inserted into the feeding tube, directed along the inside of the tube to reach the blockage, and a rotating motion of the device (manually generated by the operator) mechanically acts on the occlusion to restore the tube patency. All Medline Quick-Clear Wand are offered non-sterile and are prescription only.

Indications for Use

Medline Quick-Clear Wand is intended to be used by health care providers to restore and maintain patency of gastrostomy tubes (G-Tubes), jejunostomy tubes (J-Tubes), and percutaneous endoscopic (PEG) tubes that may be used in infant patients over 10kg, children, adolescents, and adults.

Summary of Technological Characteristics Compared to those of the Predicate Device

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Device Characteristic	Proposed Device	Predicate Device (K905164)	Comparison Analysis
Product Name	Medline Quick-Clear Wand	Tube DeClogger	N/A
Intended Use	Intended for use in restoring and maintaining patency of feeding tubes.	Intended for use in restoring and maintaining patency of feeding tubes.	Same
Indications for Use	Medline Quick-Clear Wand is intended to be used by health care providers to restore and maintain patency of gastrostomy tubes (G-Tubes), jejunostomy tubes (J-Tubes), and percutaneous endoscopic (PEG) tubes that may be used in infant patients over 10kg, children, adolescents, and adults.	It is intended to be used by heath care providers to restore and maintain patency of gastrostmy tubes (G-Tubes), jejunostomy tubes (J-Tubes), and percutaneous endoscopic gastrostomy (PEG) tubes.	Same
Regulation Name/Number	21 CFR §876.5980 Gastrointestinal tube and accessories	21 CFR §876.5980 Gastrointestinal tube and accessories	Same
Product Code	KNT	KNT	Same
Materials	Medical grade polypropylene	Not found	N/A
Design Features	Two-piece design. Color coded only in handle. Made with flexible plastic. Markings in centimeters. Compatible with ENFit devices. Two (2) length sizes. Five (5) French sizes. Disc to prevent over-insertion. Rounded tip. Description, SKU, and ENFit compatibility are printed on handle.	One-piece design. Color coded on the complete assembly. Made with flexible plastic. Markings in centimeters. Two (2) length sizes. Five (5) French sizes. Disc to prevent over-insertion. Rounded end.	Similar

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<table>
<tr><td></td><td></td><td></td><td></td></tr>
<tr><td>Product Configurations</td><td>
<table>
<tr><th>Item</th><th>Size (FR)</th><th>Length (cm)</th></tr>
<tr><td>ENT911-Blue*</td><td>14-16</td><td>39.5</td></tr>
<tr><td>ENT912-Yellow</td><td>16-18</td><td>39.5</td></tr>
<tr><td>ENT913-Green</td><td>20-22</td><td>39.5</td></tr>
<tr><td>ENT921-Brown*</td><td>14-16</td><td>21.5</td></tr>
<tr><td>ENT922-Orange</td><td>18-24</td><td>21.5</td></tr>
</table>
*ENFit compatible</td><td>
<table>
<tr><th>Item</th><th>Size (FR)</th><th>Length (cm)</th></tr>
<tr><td>911-Blue</td><td>14-16</td><td>39.5</td></tr>
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<tr><td>913-Green</td><td>20-22</td><td>39.5</td></tr>
<tr><td>921-Brown</td><td>14-16</td><td>21.5</td></tr>
<tr><td>922-Orange</td><td>18-24</td><td>21.5</td></tr>
</table>
</td><td>Same</td></tr>
<tr><td>Packaging</td><td>Single paper-poly peel pouch.</td><td>Single paper-poly peel pouch.</td><td>Same</td></tr>
<tr><td>Performance Characteristics</td><td>The following performance characteristics are equivalent to the predicate device:
Flexural strength.
Stem tensile strength.
Dimensions.
Marking accuracy.
Ability to unclog.</td><td>The following performance characteristics are equivalent to the proposed device:
Flexural strength.
Stem tensile strength.
Dimensions.
Marking accuracy.
Ability to unclog.</td><td>Same</td></tr>
<tr><td>Prescription vs. OTC</td><td>Prescription only</td><td>Prescription only</td><td>Same</td></tr>
<tr><td>Contact Durations</td><td>< 24 hours</td><td>< 24 hours</td><td>Same</td></tr>
<tr><td>Sterile vs. Non-Sterile</td><td>Non-sterile</td><td>Non-sterile</td><td>Same</td></tr>
<tr><td>Disposable vs. Non-Disposable</td><td>Disposable</td><td>Disposable</td><td>Same</td></tr>
<tr><td>Single Use vs. Reusable</td><td>Single use</td><td>Single use</td><td>Same</td></tr>
<tr><td>Shelf Life</td><td>Yes: 3 years</td><td>No</td><td>Different</td></tr>
</table>

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Variations from the predicate device design are nonsignificant.

Summary of Non-Clinical Testing

Non- clinical verification of the Medline Quick-Clear Wand 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 to the predicate, Tube DeClogger (K905164).

A summary of the testing performed is presented below.

Biocompatibility Testing

The biological evaluation for the Medline Quick-Clear Wand 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.* The proposed device is intended to restore and maintain patency of feeding tubes; as such, the Medline Quick-Clear Wand is only intended to operate inside feeding tubes. Therefore, the proposed device has been categorized as a surface device with indirect contact with mucosal membrane for a limited duration of contact ($\leq$ 24 hours).

The following biocompatibility tests were performed:

- Cytotoxicity – MEM Elution Using L-929 Mouse Fibroblast Cells per ISO 10993-5: 2009 "Biological Evaluation of Medical Devices-Part 5: Tests for in vitro Cytotoxicity."
- Sensitization – Guinea Pig Maximization Sensitization Test per ISO 10993-10: 2010: "Biological Evaluation of Medical Devices- Part 10: Tests for Irritation and Skin Sensitization."
- Irritation – Intracutaneous Irritation 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 Clear Wand 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.

Performance Testing (Bench)

To evaluate the performance of Medline Quick-Clear Wand, the proposed device was subjected to the following performance testing:

- Flexural testing per ASTM D790-17 - *Standard Test Methods For Flexure Properties Of Unreinforced Plastics And Electrical Insulating Materials,**
- Seal strength testing per ASTM F88/F88M-15 - *Standard Test Method For Seal Strength Of Flexible Barrier Materials*,

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- Marking accuracy,*
- Stem tensile strength,*
- Handle connection strength,
- Metrology*, and
- Simulated use testing.*

**Predicate device included for comparison in testing.*

Functional performance testing was performed on the final finished form of the proposed devices and the results demonstrate that all acceptance criteria were met.

Other Testing

- Bioburden: Environmental controls and bioburden monitoring supports safe bioburden levels for the indications for use.
- Phthalates: Phthalates testing supports that Medline Quick-Clear Wand is nor made with DEHP or BPA.
- Stability: Stability testing supports a shelf life of three (3) years.

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-Clear Wand is substantially equivalent to the predicate device, Tube DeClogger (K905164).