April 30, 2019

NeoMed, Inc.
Melinda Harrison Smith, RAC, ASQ-CBA
Vice President, Quality and Regulatory Affairs
100 Londonderry Court, Suite 112
Woodstock, GA 30188

Re: K183540
Trade/Device Name: Oral/Enteral Syringes with ENFit® connector (12 mL to 60 mL) and Low Dose Tip Oral/Enteral Syringes with ENFit® connector (1 mL to 6 mL)
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: II
Product Code: PNR
Dated: March 25, 2019
Received: March 27, 2019

Dear Melinda Harrison Smith:

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,

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

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)*

K183540

Device Name
Oral/Enteral Syringes with ENFit® connector (12 mL to 60 mL) and
Low Dose Tip Oral/Enteral Syringes with ENFit® connector (1 mL to 6 mL)

Indications for Use *(Describe)*

Single Use Oral/Enteral Syringes with ENFit Connector (provided sterile and non-sterile):

The device is indicated for use as a dispenser, a measuring device and a fluid transfer device. It is used to deliver fluids into the body orally or enterally. It is intended to be used in clinical and non-clinical settings by users ranging from clinicians to laypersons in all age groups.

Reusable Oral/Enteral Syringes with ENFit Connector (provided non-sterile):

The device is indicated for use as a dispenser, a measuring device and a fluid transfer device. It is used to deliver fluids into the body orally or enterally. It is intended to be used multiple times in non-clinical settings by users ranging from clinicians to laypersons in all age groups. The device is indicated for single patient use only.

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."

TRADITIONAL 510(K) SUMMARY (21 CFR § 807.92)

I. SUBMITTER

NeoMed, Inc.
100 Londonderry Court
Suite 112
Woodstock, GA 30188
Tel: 770-516-2225
Fax: 770-516-2448

Contact: Melinda Smith, MS, RAC, CBA
msmith@neomedinc.com

Date Prepared: 18 December 2018

Establishment Registration Number: 3006520777

II. DEVICE

Trade Name: Oral/Enteral Syringes with ENFit® connector (12 mL to 60 mL) and Low Dose Tip Oral/Enteral Syringes with ENFit® connector (1 mL to 6 mL)

Common Name: Enteral Syringe with Enteral Specific connector

Classification Name: Gastrointestinal tube and accessories (21 CFR § 876.5980)

Regulatory Class: II

Product Code : PNR

III. PREDICATE DEVICE

Oral/Enteral Syringes with ENFit™ connector (12 mL to 100 mL) and Low Dose Tip Oral/Enteral Syringes with ENFit™ connector (0.5 mL to 6 mL) (K161039)

Predicate device has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

NeoMed Oral/Enteral Syringes with ENFit® connector (12 mL to 60 mL) are standard piston style syringes consisting of a syringe barrel with integral ENFit syringe tip, syringe plunger, syringe gasket, and supplied sterile or non-sterile, and single use or multiuse. They are provided in varying colors and sizes ranging from 12 mL to 60 mL nominal capacity. The integral syringe tip is a female ENFit connector which is compatible only with enteral access devices or accessories having ENFit compliant or compatible male connectors to form a dedicated system that prevents wrong-route administration of fluids.

NeoMed Low Dose Tip Oral/Enteral Syringes with ENFit® connector (1 mL to 6 mL) are standard piston style syringes consisting of a syringe barrel with integral ENFit syringe tip that has the additional low dose tip design feature, syringe plunger, syringe gasket, and supplied sterile or non-sterile, and single use or multiuse. They are provided in varying

colors and sizes ranging from 1 mL to 6 mL nominal capacity. The integral syringe tip is a female ENFit connector with the additional low dose tip design feature which is compatible only with enteral access devices or accessories having ENFit compliant or compatible male connectors to form a dedicated system that prevents wrong-route administration of fluids.

Reusable Standard ENFit Syringes (12 mL to 60 mL) and reusable Low Dose Tip ENFit Syringes (1 mL to 6 mL) are supplied non-sterile and are intended for single patient use. They are provided in varying colors and sizes ranging from 1 mL to 60 mL nominal capacity.

V. INDICATIONS FOR USE

Single Use Oral/Enteral Syringes with ENFit Connector (provided sterile and non-sterile):
The device is indicated for use as a dispenser, a measuring device and a fluid transfer device. It is used to deliver fluids into the body orally or enterally. It is intended to be used in clinical and non-clinical settings by users ranging from clinicians to laypersons in all age groups.

Reusable Oral/Enteral Syringes with ENFit connector (provided non-sterile):
The device is indicated for use as a dispenser, a measuring device and a fluid transfer device. It is used to deliver fluids into the body orally or enterally. It is intended to be used multiple times in non-clinical settings by users ranging from clinicians to laypersons in all age groups. The device is indicated for single patient use only.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE

Oral/Enteral Syringes with ENFit connector (12 mL to 60 mL), and Low Dose Tip Oral/Enteral Syringes with ENFit connector (1 mL to 6 mL) have identical designs, principles of operation, materials, patient populations and use environments (however, no longer under the supervision of a clinician) as well as similar indications for use as the predicate devices cleared per K161039.

VII. PERFORMACE DATA (BENCH)

The following performance testing was conducted on the Oral/Enteral Syringes with ENFit connector and Low Dose Tip Oral/Enteral Syringes with ENFit connector:

- Finished Device
  - Risk Analysis including design, use and process FMEA (Failure Modes and Effects Analysis) in accordance with ISO 14971:2007
  - Human Factors and Usability Validation
  - Biocompatibility
    - ISO 10993-5: Cytotoxicity
    - ISO 10993-10: Irritation and sensitization
    - ISO 10993-11: Acute Toxicity
  - Chemical Testing
    - Extractables and Leachables
  - Reusability
    - Cleaning Instructions Validation
    - Use Cycle Parameters Study
  - Finished Device Verification Testing
    - Critical Dimension verification
    - Ink Adhesion
    - ISO 7886

- Capacity Tolerance
- Graduated Scale
- Piston Fit in Barrel
- Air and Liquid Leakage Testing

▪ Direct Oral Administration Dosing Accuracy Testing

- Syringe Tip (ISO 80369-3 (ENFit) connector)
  - o Enteral Connector Misconnection Assessment
  - o Human Factors Validation Study (Standard ENFit)
  - o Dimensional verification to ISO 80369-3
  - o Liquid leakage testing
  - o Resistance to stress cracking
  - o Resistance to separation from axial load
  - o Resistance to separation from unscrewing
  - o Resistance to overriding
  - o Disconnection by unscrewing

- Syringe Tip (ISO 80369-3 (ENFit) connector with Low Dose Tip Design Feature)
  - o Low Dose Tip Misconnection Risk Management Report
  - o Usability Study for Low Dose Syringe Tip Design Feature
  - o Low Dose Tip Oral/Enteral Syringe Design Dosing Accuracy Testing
  - o Dimensional verification to ISO 80369-3
  - o Liquid leakage testing
  - o Resistance to stress cracking
  - o Resistance to separation from axial load
  - o Resistance to separation from unscrewing
  - o Resistance to overriding
  - o Disconnection by unscrewing

VIII. CONCLUSIONS

NeoMed's Oral/Enteral Syringes with ENFit® connector (12 mL to 60mL) and Low Dose Tip Oral/Enteral Syringes with ENFit® connector (1 mL to 6 mL) are substantially equivalent to NeoMed's Oral/Enteral Syringes with ENFit™ connector (12 mL to 100mL) and Low Dose Tip Oral/Enteral Syringes with ENFit™ connector (1 mL to 6 mL) cleared per K161039.