DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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June 17, 2016

NeoMed, Inc.
Melinda Harrison Smith
Director, Quality and Regulatory Affairs
100 Londonderry Ct, Suite 112
Woodstock, GA 30188

Re: K161039
Trade/Device Name: NeoConnect Oral/Enteral Syringes with ENFit Connector (12 mL to 100 mL) And NeoConnect Low Dose Tip Oral/Enteral Syringes with ENFit Connector (0.5 mL to 6 mL)
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: Class II
Product Code: PNR
Dated: April 11, 2016
Received: April 13, 2016

Dear Melinda 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. 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)
K161039

Device Name
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)

Indications for Use (Describe)

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 or home care settings by users ranging from clinicians to laypersons (under the supervision of a clinician) in all age groups.

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

I. SUBMITTER

NeoMed, Inc.
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Woodstock, GA 30188
Tel: 770-516-2225
Fax: 770-516-2448

Contact: Melinda Harrison Smith, RAC, CBA
mharrison@neomedinc.com

Date Prepared: 10 June 2016

Establishment Registration Number: 3006520777

II. DEVICE

Trade Name: Oral/Enteral Syringes with ENFit® connector (12 mL to 100mL) and Low Dose Tip Oral/Enteral Syringes with ENFit® connector (0.5 mL to 6 mL)

Common Name: Oral/Enteral Syringe

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

Regulatory Class: II

Product Code : PNR

III. PREDICATE DEVICE

NeoMed NeoConnect™ Enteral Syringes with ENFit™ Connector and compatible NeoSecure™ Tip Caps (K152857)

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

IV. DEVICE DESCRIPTION

NeoMed Oral/Enteral Syringes with ENFit® connector (12 mL to 100 mL) are standard piston style syringes consisting of a syringe barrel (vented or non-vented) with integral ENFit® syringe tip, syringe plunger, and syringe gasket. They are supplied in sizes ranging from 12 mL to 100 mL nominal capacity, sterile or non-sterile, with or without a syringe tip cap, and in varying colors. The integral syringe tip is a female ENFit® connector designed to be 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 (0.5 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, and syringe gasket. They are supplied in sizes ranging from 0.5 mL to 6 mL nominal capacity, sterile or non-sterile, with or without a syringe tip cap, and in varying colors. The integral syringe tip is a female ENFit® connector with the additional low dose tip design feature designed to be 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.

V. INDICATIONS FOR USE

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 or home care settings by users ranging from clinicians to laypersons (under the supervision of a clinician) in all age groups.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE

Oral/Enteral Syringes with ENFit® connector (12 mL to 100mL) and Low Dose Tip Oral/Enteral Syringes with ENFit® connector (0.5 mL to 6 mL) have similar intended use and designs as well as identical principles of operation, materials, patient populations and use environments as the predicate device K152857.

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
  - o Risk Analysis including design, user and process FMEA (Failure Modes and Effects Analysis) in accordance with EN ISO 14971:2012
  - o Human Factors and Usability Validation
  - o Biocompatibility
    - ☒ ISO 10993-5: Cytotoxicity
    - ☒ ISO 10993-10: Irritation and sensitization
    - ☒ ISO 10993-11: Acute Toxicity
  - o Chemical Testing
    - ☒ Extractables and Leachables
  - o 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)
  - Enteral Connector Misconnection Assessment
  - Human Factors Validation Study (Standard ENFit®)
  - Dimensional verification to ISO 80369-3
  - Liquid leakage testing
  - Resistance to stress cracking
  - Resistance to separation from axial load
  - Resistance to separation from unscrewing
  - Resistance to overriding
  - Disconnection by unscrewing

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

VIII. CONCLUSIONS

NeoMed Oral/Enteral Syringes with ENFit® connector (12 mL to 100mL) and Low Dose Tip Oral/Enteral Syringes with ENFit® connector (0.5 mL to 6 mL) are substantially equivalent to the NeoMed NeoConnect™ Enteral Syringes with ENFit® Connector and compatible NeoSecure™ Tip Caps (K152857).