K122373

July 30, 2012

NEOMED

SEP 20 2012

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT	NeoMed, Inc. FDA Owner/Operator #10022926 Establishment Registration #3006520777 100 Londonderry Court Suite 112 Woodstock, GA 30188 Tony Lair, President Tel: 770-516-2225 Fax: 770-516-2448 Email: lair1@concentric.net
OFFICIAL CORRESPONDENT	Melinda Harrison, RAC NeoMed, Inc. Director of Quality and Regulatory Affairs 100 Londonderry Court Suite 112 Woodstock, GA 30188 Tel: 770-516-2225 Fax: 770-516-2448 Email: mharrison@neomedinc.com
TRADE NAME:	NeoMed Oral / Enteral Syringe (0.5ml to 100ml)
CLASSIFICATION NAME:	Piston Syringe
DEVICE CLASSIFICATION	Class II per 21 CFR §880.5560
PRODUCT CODE	FMF
PREDICATE DEVICE NAME	NeoMed Sterile Syringe (K092908)

SUBSTANTIAL EQUIVALENCE:
The principle device of this 510(k) premarket notification is the result of device modification (increase of product family size range) to the predicate device K092908 which were conducted in accordance with Quality System Regulations, 21 CFR 820.

The NeoMed Oral / Enteral Syringes ranging from 0.5ml to 100ml are substantially equivalent to the predicate device, given that both the principle and predicate devices:

- have the same indications for use
- have the same method of operation to dispense, measure and transfer fluids

- meet the applicable requirements of ISO 7886-1 and ISO 7886-2
- have the same materials which comply with ISO10993-1 as applicable to the intended use of the device
- are sterilized to Sterility Assurance Level (SAL) of 10^{-6}
- demonstrate equivalent performance during design verification testing
- meet the applicable requirements of ISO 80369-1

Design Verification testing as a result of the risk analysis has demonstrated that the NeoMed Oral / Enteral Syringes ranging from 0.5mL to 100mL are functionally equivalent to predicate NeoMed Sterile Syringes and the new range of sizes do not affect safety or effectiveness when compared to the predicate device.

DESCRIPTION OF THE DEVICE:
The NeoMed Oral / Enteral Syringe is specifically designed for administration of enteral liquids to neonatal and small pediatric patients. The NeoMed Oral / Enteral Syringe is a standard piston syringe which is incompatible with luer-lock and intravenous devices. The NeoMed Oral / Enteral Syringes are compatible with NeoMed enteral-only connectors, the NeoMed extension sets and NeoMed feeding tubes to form a dedicated system that prevents wrong-route administration of non-IV fluids and other competitive enteral/feeding tube, extension set type products that do not utilize a luer-lock system. They possess translucent barrels to provide visualization of fluid contents and volume, and patented orange lettering/gradient markings which coordinate with NeoMed orange extension sets and feeding tubes. NeoMed Oral / Enteral Syringes are manufactured as a single piece molded barrel that does not rely on adapters to create an oral tip. The NeoMed Oral / Enteral Syringes possess design features that prevent connectivity to luer type devices and hence prevents the chance that a feeding tube could be infused into the IV line.

The NeoMed Oral / Enteral Syringe device consists of the following components:

- Syringe Barrel
- Syringe Plunger
- Syringe Gasket
- Syringe Tip
- Syringe Cap

INDICATIONS FOR USE:
The device is indicated for use as a dispenser, a measuring device and an oral fluid transfer device. It is used to inject fluids into the body via extension sets and feeding tubes in neonatal and small pediatric patients.

PERFORMANCE DATA:
The NeoMed Oral / Enteral Syringe materials that come in direct contact with the patient have a long history of use in syringe manufacturing and are biocompatible according to ISO 10993 test results. Design verification test results demonstrate that the NeoMed Oral / Enteral Syringe performs as intended and the extended size range from the predicate does not affect safety or effectiveness.

CONCLUSION:
Based on the method of operation, indications for use, materials of construction and performance testing, it can be concluded that the NeoMed Oral / Enteral Syringes ranging from 0.5ml to 100ml are equivalent to the predicate NeoMed Sterile Syringe with respect to intended use and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 20 2012

NeoMed, Incorporated
Ms. Melinda Harrison
Director of Quality and Regulatory Affairs
100 Londonderry Court, Suite 112
Woodstock, Georgia 30188

Re: K122373
Trade/Device Name: NeoMed Oral / Enteral Syringe (0.5ml to 100ml)
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: August 30, 2012
Received: September 4, 2012

Dear Ms. Harrison:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

For

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known):

Device Name: **NEOMED ORAL / ENTERAL SYRINGE**

Indications For Use:

The device is indicated for use as a dispenser, a measuring device and an oral fluid transfer device. It is used to inject fluids into the body via extension sets and feeding tubes in neonatal and small pediatric patients.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

9/12/12

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K122373

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