K100288 Page 1 of 2

NEOMED incorporated

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.

DATE	August 2, 2010
APPLICANT	NeoMed 100 Londonderry Ct Suite 112 Woodstock, GA 30188 Tony Lair, President Tel: 888-876-2225 e-mail: lair1@concentric.net
OFFICIAL CORRESPONDENT	Penny Northcutt, RAC, CQA Regulatory Consultant for NeoMed, Inc. REGSolutions, LLC Tel: 678-428-6978 Fax: 678-513-0937 e-mail: pennynorthcutt@theregsolutions.com
TRADE NAME	NeoMed Enteral Only Extension Set
CLASSIFICATION NAME	Tubes, Gastrointestinal (and accessories)
DEVICE CLASSIFICATION AND PRODUCT CODE	Class II per 21 CFR §876.5980 Gastroenterology/Urology Product Code: KNT
PREDICATE DEVICE NAME	Respironics Enteral Only Extension Set, K082654

AUG 3 - 2010

SUBSTANTIAL EQUIVALENCE:

The NeoMed Enteral Only Extension Set is substantially equivalent to the Respironics Enteral Only Extension Set cleared under K082654.

Both devices have similar indications for use, materials, product design, and method of operation. Bench testing has demonstrated that the NeoMed Enteral Only Extension Set is functionally equivalent to the proposed predicate extension set. Any minor differences have no impact affect safety or effectiveness of the NeoMed Enteral Only Extension Set.

NEOMED incorporated

DESCRIPTION OF THE DEVICE:
The NeoMed Enteral Only Extension Set is a sterile disposable for single patient use only device designed to help minimize the potential for inadvertent delivery of enteral feedings through the intravenous route. The device consists of flexible PVC tubing designed to connect existing feeding tubes (nasogastric, oralgastric, gastric, etc) to various delivery systems in including pumps and syringes. The set consists of tubing with an enteral connector (catheter tip) and an oral syringe connector not compatible with IV tubing or stopcocks. The NeoMed Enteral Only Extension Set provides an orange stripe for easy quick identification of enteral feeding lines as well as an "Enteral Only" tag and slide clamp to provide the additional safety assurance for connection errors.

INTENDED USE/INDICATIONS FOR USE:
The NeoMed Enteral Only Extension Set is intended for use as an extension set for nasogastric/oralgastric or gastric tube enteral feeding tubes, incorporating safety connectors which help mitigate the risk of accidental connection of an I.V. system to the enteral system or the enteral system to an I.V. system.

This device is indicated for use in neonatal and pediatric patients in connection with an enteral feeding tube to provide nutrition via nasal or oral gastric placements.

PERFORMANCE DATA:
The NeoMed Enteral Only Extension Set materials have a long history of use in extension set and feeding tube manufacturing and are biocompatible. Design verification functional test results demonstrate that the NeoMed Enteral Only Extension Set performs its intended use.

The functional tests conducted were mechanical: tensile, strain, elongation and physical/properties testing comprised of dimensional verification, flow rate, and hub compatibility. Packaging challenges for package integrity and product stability were conducted with aging studies. All materials have been evaluated in accordance with ISO 10993-1: Biological Evaluation of Medical Devices – part 1: Evaluation and Testing and the three tests conducted – cytotoxicity, sensitization, and irritation pass.

CONCLUSION:
Based on the performance testing, it can be concluded that the NeoMed Enteral Only Extension Set is equivalent to the Respironics Enteral Only Extension Set predicate with respect to intended use, materials, design, and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G6
Silver Spring, MD 20993-0002

Neomed, Inc.
c/o Ms. Penny Northcutt
Executive Director
REGSolutions, LLC
717 Lakeglen Drive
SUWANEE GA 30024

AUG 3 - 2010

Re: K100288
Trade/Device Name: Neomed enteral only extension set
Regulation Number: 21 CFR §876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: Class II
Product Code: KNT
Dated: July 28, 2010
Received: July 29, 2010

Dear Ms. Northcutt:

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,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K100288

Indications for Use

AUG 3 - 2010

K100288

Device Name: Neomed Enteral Only Extension Set

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K100288