FEB 12 2014

5.0 510(k) Summary

In accordance with 21 CFR 807.87(h) and 21 CFR 807.92 the 51(k) Summary for the Gravity Enteral Feeding Sets is provided below.

Date Prepared:	June 28, 2013
Device Common Name:	Gastrointestinal tubes and accessories
Device Proprietary Name:	METRIXCARE™
Submitter:	The Metrix Company 4400 Chavenelle Rd Dubuque, IA 52002
Contact:	Nicholas J. Specht Quality Assurance Manager The Metrix Company Phone: 563-556-8800 Fax: 563-556-4704 nspecht@metrixco.com
Classification Regulation:	21 CFR 876.5980
Panel:	Gastroenterology/Urology
Product Code:	KNT
Indication for Use:	The device is intended to deliver liquid nutritional formulas or water to a patient's enteral access device (feeding tube).

Device Description:

The sets are constructed from flexible, medical grade, Non-DEHP tubing in various configurations with a stepped connector at one end. One configuration may include an Enteral solution container constructed of a laminate material with a stepped connector to connect to a gastric tube (or an extension set) or another configuration may simply be an administration set which connects the patient gastric tube to the nutrition liquid container.

Performance Testing Summary:

Stepped Adaptor: The stepped adaptor meets the requirements of AAMI/ANSI ID54:1996/(R)2012, Enteral Feeding Set Adapters and Connectors.

Safety Screw Connector: The safety screw conncector meets the requirements of AAMI/ANSI/ISO 80369-1, Small-Bore Connectors For Liquids and Gases In Healthcare Applications – Part 1: General Requirements.

The following bench test reports are provided in Appendix A and B of this submission to support the performance characteristics of the proposed sets.

1) Validation 703V – A study of the accuracy of the current drop factor given on gravity feed sets.
2) Validation Protocol 868V: A Study to qualify the process to manufacture Gravity Set w/ Bag.

Substantial Equivalence:

The Gravity Enteral Feeding Sets are substantially equivalent to commercially marketed Abbott Nutrition sets in terms of principle of materials, operation, and intended use.

The Metrix Company
Traditional 510(k) Submission

Technological Charachteristics:

TECHNOLOGICAL CHARACTERISTICS OF DEVICE COMPARED TO PREDICATE

THE METRIX COMPANY MODEL SEEKING CLEARANCE	DESCRIPTION	PREDICATE MODEL: ROSS LABORATORIES AND/OR ABBOTT	DIFFERENCES IN DESIGN	DIFFERENCES MATERIALS (All materials used in all the product are listed in Table B.)	DIFFERENCES IN CHEMICAL COMPOSITION	DIFFERENCES IN ENERGY SOURCE
70010	500ml Enteral Bag with Gravity Set	51584	None - Product and component dimensions are identical.	None - Both made from the same materials from the same source.	None - Both made from the same materials from the same source.	None - Flow rate of both determined by gravity.
70020	1000ml Enteral Bag with Gravity Set	00056	None - Product and component dimensions are identical.	None - Both made from the same materials from the same source.	None - Both made from the same materials from the same source.	None - Flow rate of both determined by gravity.
70030	1000ml Enteral Bag with Screw Cap & Gravity Set	00089	None - Product and component dimensions are identical.	None - Both made from the same materials from the same source.	None - Both made from the same materials from the same source.	None - Flow rate of both determined by gravity.
70040	Gavity Set with Feeding Cap	00061	None - Product and component dimensions are identical.	None - Both made from the same materials from the same source.	None - Both made from the same materials from the same source.	None - Flow rate of both determined by gravity.
70050	Gravity Set with Cross Screw Connector	62562	None - Product and component dimensions are identical.	None - Both made from the same materials from the same source.	None - Both made from the same materials from the same source.	None - Flow rate of both determined by gravity.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

February 12, 2014

The Metrix Company
Nicholas Specht
Quality Assurance Manager
4400 Chavenelle Road
Dubuque, IA 52002

Re: K132424
Trade/Device Name: Gravity Enteral Feeding Sets
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT
Dated: January 6, 2014
Received: January 7, 2014

Dear Nicholas Specht,

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,

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

4.0 Indications For Use Statement

510(k) Number (if known): K132424

Device Name: Gravity Enteral Feeding Sets

Indications For Use:

The device is intended to deliver liquid nutritional formulas or water to a patient's enteral access device (feeding tube).

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

Benjamin R. Fisher -S
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