MAR 2 9 2012

Acta Medical, LLC

Date Submitted:	September 28th, 2011
Submitted By:	Acta Medical, LLC Inc 15 Minneakoning Road, Suite 203 Tel: 908-399-0279 Fax:908-788-9788
Submitter Contact:	Aaron Compton Acta Medical, LLC Contact email: acatutd@satx.rr.com Tel:214-533-1416 Fax:972-638-8549
Common Name of Device:	Enteral Set
Predicate Device:	Promedic Pediatric Enteral feeding tubes and Extension sets (K092628) Dynarex Enteral Sets For Gravity and Pump Use(K082863) Truecare Biomedix Intravascular Administration Set (K111351)
Panel:	Tubes, Gastrointestinal (and accessories)
Product Code:	KNT
Device Classification:	Class II
Classification Reference:	21CFR 876.5980
Appropriate Classification Panel:	Gastroenterology/Urology
Manufacturing Location:	Yangzhou Wei De Li Trade Co. Ltd. Li Xin Bridge Touqiao Township. Yangzhou City, Jiangsu Province. China Tel: +86-514-87897887 Fax: +86-514-87889967

Name & Model Numbers of Devices:

1. Enteral Administration Set with Solution Container, 1200ml capacity (VDENT001)

2. Enteral Administration Set (VDENTS001)

3. Enteral Extension Set with Minitube Connector(VDENT8-1222)

Device Description:

Acta Enteral Sets are constructed from flexible, medical grade, Non-DEHP tubing and have various different connectors at each end of the tubing. One configuration may include an Enteral solution container constructed from same PVC material as the tubing with a Christmas tree connector to connect to a gastric tube (or an extension set) or another configuration may simply be an extension set which connects to patient gastric tube to the nutrition liquid delivery system. The following three configurations are most common, however, other configurations may be manufactured based on customer demand. (Further details, photos, drawings provided in Device Description, Section XI)

1. *A complete solution delivery system:* This consists of, a solution container, integrated delivery set and a Christmas tree connector to connect to the gastric tube or to an extension set
2. *Enteral Administration Set*: This consists of a delivery set with a spike to connect to a nutrition solution storage container and a Christmas tree connector to connect to gastric tube or an extension set
3. *Enteral Extension Set:* This consists of flexible PVC tubing set with proximal connector which can accept a standard Christmas tree connector and a distal connector designed to fit a custom gastric tube

Device Intended Use: Enteral Set

To deliver liquid nutrition formula from storage container to an enteral access device (feeding tube)

Substantial Equivalence:

Acta Medical, LLC Enteral Set is substantially equivalent to predicate devices as follows:

A complete solution delivery system and Enteral Administration Set is substantially equivalent to predicate device Dynarex Enteral Set for Gravity and Pump Use (K082863) in its design, intended use, function, materials, performance
Enteral Extension Set is substantially equivalent to Promedic, Pediatric Enteral Feeding tubes and Extension sets (K092628) in its design, intended use, function, materials, performance
Enteral Set is substantially equivalent to Truecare Biomedix Intravascular administration set (K111351) in its materials and manufacturer. Enteral Sets are constructed from same materials (non-DEHP PVC, Silicone, ABS) and manufactured by same manufacturer (Yangzhou Wei De Li) at the same manufacturing location as K111351.

Acta Medical, LLC Enteral Sets construction materials have been tested for biocompatibility, DEHP, extractables and leachables, physico chemical tests for plastics. Furthermore, the manufactured sets have been tested per ISO 8536-4 for leak test, tensile strength.. Acta Medical, LLC Enteral Sets meets all the requirements for biocompatibility (ISO 10993-1) and applicable performance criteria (ISO 8536-4)

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

Mr. Aaron Compton
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929 Arbor Downs Drive
PLANO TX 75023

MAR 29 2012

Re: K112863
Trade/Device Name: Enteral Set
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT
Dated: March 22, 2012
Received: March 22, 2012

Dear Mr. Compton:

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, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112863

Device Name: Enteral Set

Indications For Use: To deliver liquid nutrition formula from storage container to an enteral access device (feeding tube)

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)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K112863