JUL 28 2014

510(k) Summary (As required by 21 CFR 807.92(a))

Applicant and Correspondent

Name: Generica Medical International
Address: 1910 D Street
La Verne, CA 91750

Contact Person: Len Hoffstetter
President

Phone: (909) 596-6785 (Office)

Date of Preparation: July 25, 2014

Manufacturer

Conod Medical Co., Limited
No. 38 Hongfeng Road
Changshu City, Jiangsu, China

Registration#: 3006673317

Name of Device

Trade/Proprietary/Model Name:	Generica Medical Enteral Delivery Pump Bag Set, Generica Medical Enteral Delivery Pump Spike Set, Generica Medical Enteral Delivery Gravity Bag Set
Common Name:	Enteral Feeding Sets
Classification Name:	Gastrointestinal tube and accessories
Classification Regulation:	876.5980
Panel:	Gastroenterology/Urology
Product Code:	KNT FPD
Recognized Performance Std:	None

Device to Which New Device is Substantially Equivalent

Device Name:	Dynarex Enteral Feeding Sets for Gravity & Pump Use
Manufacturer:	Dynarex
Reference:	K082863

510(k) SUMMARY (Continued)

Device Description

The Generica Medical International's line of Enteral Feeding Sets consists of the following:

1. Generica Medical Enteral Delivery Pump Bag Set,
2. Generica Medical Enteral Delivery Pump Spike Set,
3. Generica Medical Enteral Delivery Gravity Bag Set

The Generica Medical Enteral Delivery Pump Spike Set with the Cross Spike Connector is compatible with SpikeRight® and SpikeRight® enteral feeding systems.

The Generica Medical Enteral Delivery Pump Bag Set has a twist cap. The vinyl bag features a rigid wide-mouth angled funnel opening that makes pouring easy and helps prevent spills and waste. The 1000 mL formula vinyl bag has 50 mL graduations to make it easier for reading and better accuracy when filling.

The Generica Medical Enteral Delivery Gravity Bag Set has a twist cap. The vinyl bag features a rigid wide-mouth angled funnel opening that makes pouring easy and helps prevent spills and waste. Bag graduations are in 50 mL increments for easier readings and allow for better accuracy when filling

Statement of Intended Use

The Enteral Feeding Sets are intended to dispense liquid nutrients (feeding solutions) at a user controlled rate. These enteral feeding sets interface with the patients feeding tube and may use gravity or an enteral feeding pump to dispense feeding solution. The enteral feeding sets may include a bag to contain the feeding solution and/or spike to connect to a pre-filled container.

Summary of Technological Characteristics

The Intended Use statement of the Generica Medical Enteral Feeding Sets is identical to that of the predicate. The materials of construction used in the Generica Medical Enteral Feeding Sets are identical to those of the predicate device. Performance testing has demonstrated that the products' efficacy and effectiveness is the same as the predicate device.

Parameter Description	Predicate Device: Dynarex Enteral Feeding Sets	Subject Device: Generica Medical Enteral Feeding Set	Comparison of Subject Device to Predicate
Description	Dynarex Enteral Delivery Pump Spike Set is the ideal Enteral Feeding Set if you do not need the feeding bag. Dynarex Enteral Delivery Pump Spike Set includes the components needed to open the nutritional bag, connect the tubing to the pump and the feeding set adapter to the feeding tube. The Dynarex Enteral Feeding Gravity Bag Set is an effective method to deliver liquid nutrition to patients. This enteral feeding set features a feeding set adapter with a protective cap, a locking tip, and gravity forced formula flow.	The Generica Medical Enteral Delivery Pump Bag Set has a twist cap. The vinyl bag features a rigid wide-mouth angled funnel opening that makes pouring easy and helps prevent spills and waste. The 1000 mL formula vinyl bag has 50 mL graduations to make it easier for reading and better accuracy when filling. The Generica Medical Enteral Delivery Pump Spike Set with the Cross Spike Connector is compatible with SpikeRight® and SpikeRight® enteral feeding systems. The Generica Medical Enternal Delivery Gravity Bag Set has a twist cap. The vinyl bag features a rigid wide-mouth angled funnel opening that makes pouring easy and helps prevent spills and waste. Bag graduations are in 50 mL increments for easier readings and allow for better accuracy when filling	Similar and SE

	Parameter Description	Predicate Device: Dynarex Enteral Feeding Sets	Subject Device: Generica Medical Enteral Feeding Set	Comparison of Subject Device to Predicate
Port	Bag	1200 ml	1000 ml	SE
	Spike	Spike Right	Spike Right	Same
	Drip Chamber	Clear	Clear	Same
	Distal Tip Connector	4 Step Adapter	4 Step Adapter	Same
Style	Pump Bag Set	Yes	Yes	Same
	Spike Set	Yes	Yes	Same
	Gravity Bag Set	Yes	Yes	Same
Pe	Flow rate variance	<10%	<10%	Same
Other Features	Non-Sterile	Yes	Yes	Same
	Single Patient Use	Yes	Yes	Same
	Disposable	Yes	Yes	Same

Brief description of the nonclinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence.

- The Generica Medical Enteral Feedings Sets were tested for compatibility and accuracy with the Nestle Compat and Alcor Sentinel Enteral Feeding Pumps. In addition, the accuracy of the Generica Medical Enteral Feeding Sets was compared to the predicate device at various flow rates.

Brief discussion of clinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence.

Not applicable.

Conclusion drawn for the nonclinical and clinical tests

The Generica Medical Enteral Feeding Sets have the same intended use and technological characteristics as the predicate device, Dynarex Enteral Feeding Sets. The materials of construction used in the Generica Medical Enteral Feeding Sets are substantially equivalent to those of the predicate device. Performance testing has demonstrated the product's efficacy. The Generica Medical Enteral Feeding Sets have been demonstrated to be substantially equivalent to the predicate device.

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

July 28, 2014

Generica Medical International, Inc.
Jim Barley
Director of RA/QA
1910 D Street
LaVerne, CA 91750

Re: K133077
Trade/Device Name: Generica Medical Enteral Feeding Sets
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Codes: KNT, FPS
Dated: June 30, 2014
Received: July 9, 2014

Dear Jim Barley,

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

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)*
K133077

Device Name

Generica Medical Enteral Feeding Sets

Indications for Use *(Describe)*

The Enteral Feeding Sets are intended to dispense liquid nutrients (feeding solutions) at a user controlled rate. These enteral feeding sets interface with the patients feeding tube and may use gravity or an enteral feeding pump to dispense feeding solution. The enteral feeding sets may include a bag to contain the feeding solution and/or spike to connect to a pre-filled container.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Benjamin R. Fisher -S
2014.07.28 16:51:45 -04'00'

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