K082863

JAN - 9 2009

510(K) SUMMARY

THIS SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION IS BEING SUBMITTED IN ACCORDANCE WITH THE REQUIREMENTS OF THE SAFE MEDICAL DEVICES ACT OF 1990.

Submitter	Dynarex Corporation 10 Glenshaw Street Orangeburg, NY 10962 USA Phone: 845-365-8200 Fax: 845-365-8238
Contact Person	James Hurlman
Date of Summary	09/24/2008
Trade Name	Dynarex Enteral Feeding Sets for Gravity and Pump Use
Common Name	Enteral Feeding Sets for Gravity and Pump Use
Classification Name	Gastrointestinal tube and accessories.
Predicate Device	Zevex, Inc. Enteral Feeding Sets for Gravity and Pump Use (K012147)
Device Description/ Comparison	Dynarex is substantially equivalent in safety and effectiveness to the Zevex, Inc. Enteral Feeding Sets for Gravity and Pump Use in that both products have the same principles of operation, form and function and meet the same safety requirements under Class VI testing and functional Luer taper testing as required by the referenced standard.
Intended Use	The devices in this product family are used 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 devices may include a bag to contain the feeding solution and/or a spike to connect to a pre-filled container.

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Substantial Equivalence Discussion:

The Dynarex Enteral Feed Sets are substantially equivalent to the predicate devices EnteralLite line of products.

Characteristic and parameters	Zevex, Inc. (Predicate Device)	Dynarex Corporation (New Device)
Product Code	KNT	KNT
Intended Use (Referring to entire set)	"The devices in this product family are used 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 devices may include a bag to contain the feeding solution and/or spike to connect to a per-filled container."	Same
Luer Adapter	Slip Loc design, PVC USP Class VI Material	Standard Adapter USP Class VI Material
Luer Cap	Designed to fit Slip Loc, PE	Standard design fit Same Material
Feed Tubing (All)	PVC, , USP Class VI Material	Same
Pump Tubing (Pump and Spike Set)	Silicone, , USP Class VI Material	Same
Bag Assembly (Gravity & Pump Set)	500 ml, PVC, USP Class VI Material	1000ml, PVC
	1200 ml, PVC, USP Class VI Material	1000ml, PVC
Clamp (All)	ABS	Same
Materials in Fluid Pathway (All)	USP Class VI Material	Same
Spike Adapter (Spike Set Only)	ABS, USP Class VI Material	Same
Spike Adapter Cap (Spike Set Only)	PE	Same

Summary of Testing:

Test Results

1. Intracutaneous Reactivity Test - Class VI USP — Passes
2. Systemic Injection Test - Class VI USP — Passes
3. Muscle Implantation Test - Class VI USP — Passes
4. Luer Taper Inspection - AAMI/ ANSI ID54:1996/(R)2005 Sect. 4.1 & 4.2 — Passes

The standards used by Dynarex Corporation to determine substantial equivalence are based on AAMI/ ANSI ID54:1996/(R)2005 and Class VI USP Methods. All testing meets requirements for erythema and edema scores, physical specifications and dimensions.

Conclusion:

Our evaluation concluded that the Dynarex family of Enteral Feeding Sets for Gravity and Pump Use are substantially equivalent to the predicate device and raise no new issues of Safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 9 2009

Mr. James Hurlman
Manager, Quality Assurance & Regulatory Affairs
Dynarex Corporation
10 Glenshaw Street
ORANGEBURG NY 10962

Re: K082863
Trade/Device Name: Enteral Feeding Sets for Gravity and Pump Use
Regulation Number: 21 CFR §876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT
Dated: December 23, 2008
Received: December 24, 2008

Dear Mr. Hurlman:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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; 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding os substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry.suppot/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082863

Device Name(s): Enteral Feeding Sets for Gravity and Pump Use

Indications For Use:

The devices in this product family are used 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 devices may include a bag to contain the feeding solution and/or a spike to connect to a pre-filled container. These devices are food contacting.

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)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K082863