K072652
1 of 3

Cedic

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JAN 1 8 2008

18 September 2007

510(k) Summary

510(k) owner = Cedic Srl
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This summary was prepared on September 10th 2007.

Trade Name = Enteral Feeding Spike Adapter

Common Name = Accessory for Enteral Feeding Set

Classification Name = Tube, Gastrointestinal (and Accessories) (21 CFR 876.5980, Product Code KNT)

Predicate Device = Zevex Spike Pump Set LG0010, manufactured by Zevex, Inc, Salt Lake City, UT 84123, USA

Device Description = Enteral Feeding Spike Adapter to be used for enteral administration. This device serves as a connection between the feeding container and the enteral set (gravity or pump fed).

K07-2652
2 of 3

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Materials Used:

In the food pathway = Gasket: 3-ply co-extruded material: Foamed core of foamed EPE between 2 layers of solid PE-EVA

Non-vented oval spike and revolving spike lock: ABS - HF 380 + dye Remafin violet PE43076356-ZT

Bag fitment: Soft PVC - Nakan FMA919N

Not in the food pathway = Cap for spike and bag fitment: LDPE - Riblene MM20 + dye Remafin violet PE43076356-ZT

Label: Lacquered paper 70 lb weight, printed both sides with red Pantone 185 C

Intended Use of Cedic Enteral Feeding Spike Adapter = For use in dispensing liquid nutrients (feeding solutions) by connecting an enteral feeding container to a patient's feeding tube.

Brief comparison with predicate device:

(1) The Cedic Enteral Feeding Adapter and Spike Adapter from the Zevex Enteral Feeding Set have the same intended use -- *"For use in dispensing liquid nutrients (feeding solutions) by connecting an enteral feeding container to a patient's feeding tube"*;

(2) They have similar indications for use:

Cedic Enteral Feeding Spike Adapter: *"For connecting a universal enteral spike set to a feeding container having a SpikeRight™ connection port."*

Zevex Enteral Feeding Set: [Referring to the entire set] *"The devices in this product family are used to dispense liquid nutrients (feeding solution) at a user controllable rate. These enteral feeding sets interface with the patient's 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 pre-filled container."*

It is clear from this indications for use statement that the spike adapter within the Zevex set has the same indication for use as the Cedic Enteral Feeding Spike Adapter, with the exception that the Cedic adapter is designed to connect to a feeding container having the SpikeRight™ type of connection port, whereas the Zevex design is 'universal'.

(3) Both the Cedic spike adapter and Zevex spike adapter from within the feeding set have the same therapeutic purpose of connecting an enteral feeding container to enteral feeding tube, both spike adapters being parts of enteral feeding systems that contain the same types of devices;

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(4) Both the Cedic spike adapter and Zevex spike adapter from within the feeding set have similar principles of operation, providing a food pathway between an enteral feeding container and an enteral feeding tube;

(5) All materials used in the food pathways of both devices are USP Class VI, and any colorants used are approved by the FDA for food grade applications.

From this comparison, it is concluded that the Cedic Enteral Feeding Spike Adapter is "substantially equivalent" to the spike adapter from the Zevex Enteral Feeding Set.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 18 2008

Mr. Riccardo Rossi
Technical Director / QA Manager
Cedic Srl
Via Liberazione, 63/9
Peschiera Borromeo Milan (Lomb)
ITALY 20068

Re: K072652
Trade/Device Name: Enteral Feeding Spike Adapter
Regulation Number: 21 CFR §876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT
Dated: January 14, 2008
Received: January 14, 2008

Dear Mr. Rossi:

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 of 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

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

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (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 Manufacturers, 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/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K0 + 2 6 5 –

Indications for Use

510(k) Number (if known): to be assigned

Device Name: Enteral Feeding Spike Adapter

Indications for Use:

For connecting a universal enteral spike set to a feeding container having a SpikeRight™ connection port.

Prescription Use: √ (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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K072652