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SMDA Summary – Special 510(k) Modified Device

MAR - 5 2008

Submitted by:

Nestlé HealthCare Nutrition, Inc.
12500 Whitewater Drive
Minnetonka, MN 55343

Contact Person:

Thomas A. Dold
Associate Director, Regulatory Affairs – Medical Devices
Nestlé HealthCare Nutrition, Inc.
Phone: 952.848.6480
Fax: 952.848.6319

Summary Date:

February 5, 2008

Proprietary Name:

COMPAT® DualFlo™ Enteral Delivery Pump Set with SpikeRight™ Piercing Spike and 1000 mL Water Bag

COMPAT® Y Set. Pump Set with In Line "Y: Adaptor and SpikeRight™ Piercing Spike

Common Name:

Tubes, Gastrointestinal and Accessories

CFR Reference:

21CFR§ 876.5980

Class:

II

Product Code:

KNT

Equivalent marketed device:

K940555 – Sandoz Nutrition COMPAT Enteral Feeding Pump with Hydration

K940556 - Sandoz Nutrition COMPAT Enteral Feeding Pump

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Device Description:

COMPAT® DualFlo™ Enteral Delivery Pump Set with SpikeRight™ Piercing Spike and 1000 mL Water Bag

The COMPAT Pump administration sets are designed specifically for use with the COMPAT® Enteral Pumps. The SpikeRight piercing spike with 1000 mL water bag is compatible with all SpikeRight compatible enteral feeding systems. The twist and lock feature ensures safe and effective connection and prevents inadvertent connections to IV sets. The 1000 mL formula vinyl bag with 1000 mL water bag has 50 mL graduations to make it easier for reading and better accuracy when filling. The different-colored print on the bags make it easy to identify water and formula and the nutrition orders can be written directly on the formula bag for convenience. Single Use Only.

COMPAT® Y Set. Pump Set with In Line "Y: Adaptor and SpikeRight™ Piercing Spike

The COMPAT Pump administration sets are designed specifically for use with the COMPAT® Enteral Pumps. The SpikeRight piercing spike is compatible with all SpikeRight compatible enteral feeding systems. The COMPAT pump set with the in-line "Y" adapter is DEHP and latex free. Easy to use "Y" adapter - simply disconnect "Y" adapter cap and insert syringe for flushing. The in-line "Y" saves time - no need to disconnect set from the feeding tube when flushing medications, water or bolus feeding. Ready to use. Single use only.

Intended Use:

The COMPAT® Enteral Delivery Pump Sets are intended to deliver liquid nutrition formulas or hydration to an enteral access device (a feeding tube).

Technological Characteristics:

The modified device has the same basic technological characteristics as the predicate device. The modified device is equivalent in terms of design, functionality, principles of operation, performance specifications and intended use. When compared to the unmodified device, the modified device raises no new technological issues.

Substantial Equivalence Rationale:

Based on design, technological characteristics, intended use, and extensive testing, Nestlé HealthCare Nutrition, Inc. believes that the modified device is substantially equivalent to the unmodified predicate device currently marketed under 510(k) K940555 and K940556

The modified device raises no new issues of safety or effectiveness.

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Test Conclusions:

Nestlé HealthCare Nutrition, Inc. has conducted extensive testing of the modified device to verify adherence to requirements. All test results verify that the device meets or exceeds all predetermined specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

MAR - 5 2008

Mr. Thomas A. Dold
Associate Director of Regulatory Affairs
Nestlé Healthcare Nutrition, Inc.
12500 Whitewater Dr.
MINNETONKA MN 55343

Re: K080340
Trade/Device Name: COMPAT® Enteral Delivery Pump Sets with SpikeRight™ Piercing Spike
Regulation Number: 21 CFR §876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Produce Code: KNT
Dated: February 5, 2008
Received: February 8, 2008

Dear Mr. Dold:

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 (Premarket Approval), 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

9.0 INDICATIONS FOR USE

INDICATIONS FOR USE

510(k) Number (if known): K080340

Device Name: COMPAT® Enteral Delivery Pump Sets with SpikeRight™ Piercing Spike

Indications for Use:

The COMPAT® Enteral Delivery Pump Sets are intended to deliver liquid nutrition formulas or hydration to an enteral access device (a feeding tube).

Prescription Use __X__ AND/OR (Part 21 CFR 801 Subpart D)

Over-The-Counter Use _____ (21 CFR 807 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 K080340