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510(k) Summary of Safety and Effectiveness

Submitter: Maulin Medical LLC (Sara J. Owens)
486 E. Gentry Drive,
Pueblo West, CO 81007 USA

JUL 23 2010

Contact Person: Sara J. Owens
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Device Trade Name: Guardian Connection™

Classification name: Gastrointestinal Tube and Accessories (21 CFR 876.5980)

Predicate Device: Cedic Enteral Feeding Spike Adapter (K072652)

Device Description:

The Guardian Connection is a non-sterile, reusable, plastic "U-shaped" clip designed to hold the connectors of an enteric feeding tube and an enteric feeding set together to help prevent inadvertent disconnection. The product is specifically designed to accommodate the non-IV tapered male conical stepped connectors and mating non-IV tapered female connectors commonly found on standard adult enteric feeding tubes and sets. The Guardian Connection clips around the outside of these connectors, and helps to prevent them from being pulled apart by tensile force.

Intended Use:

The Guardian Connection™ is designed for use with standard adult tapered feeding tube connectors to secure the connection.

Technological Characteristics and Comparison to Predicate Device:

The Guardian Connection is similar to the predicate device in that both are gastrointestinal tube accessories that connect enteral feeding systems. The following table compares the technological characteristics of the two devices:

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Parameter	Guardian Connection™ (This submission)	Cedic Enteral Feeding Spike Adapter (K072652)
Intended Use	For securing the connection between the standard peg connector of an enteric feeding tube and the inline connector of a nutrient delivery set.	For connecting a universal enteral spike set to a feeding container having a SpikeRight connection port.
Accessory to an enteric feeding system	Yes	Yes
Food pathway or patient contact	No	Yes
Principle of Operation	Secures the connection between an enteric feeding tube and the nutrient delivery set by clipping around the interconnection	Connects an enteric feeding container and an enteric feeding tube
Sterile	No	Yes
Usage	Single Use	Single Use

Testing Performed:

Bench testing was performed on the Guardian Connector to show that the device performs as intended. No clinical testing was performed on this device. The Guardian Connection will break away at a tensile force of approximately two pounds, and thus it can help protect the feeding tube/nutrient line from disconnection due to low-level forces that can cause the failure of this connection..

Statement of Substantial Equivalence:

The Guardian Connector is substantially equivalent to the Cedic Enteral Feeding Spike Adaptor, in that both are accessories to an enteric feeding system and both are intended to provide a secure connection in this system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Ms. Sara J. Owens
Maulin Medical LLC
486 E. Gentry Drive
PUEBLO WEST CO 81007

JUL 23 2010

Re: K101214
Trade/Device Name: Guardian Connection™
Regulation Number: 21 CFR §876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product code: FPD
Dated: April 20, 2010
Received: April 30, 2010

Dear Ms. Owens:

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,

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

Enclosure

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Indications for Use Statement

510(k) Number (if known): K101214

Device Name: Guardian Connection™

Indications for Use:

The GUARDIAN CONNECTION™ is designed to be used with standard adult tapered feeding tube connectors to secure the connection.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K101214