AUG 3 1 2004

GENERAL INFORMATION

Device Name

Trade Name:	Skin Level Gastrostomy Tube Kit (ECSL)
Common/Usual Name:	Gastrostomy Tube Kit
Classification Name:	Gastrointestinal tube and accessories

Registration Number

The Device Establishment Registration Number is 1931566.

Sponsor Name and Address

EntraCare, LLC
11315 Strang Line Road
Lenexa, KS 66215
Phone: 913-451-2234
Fax: 913-451-2363
Contact Name: Cary Dikeman
Title: President

Submission Correspondent:

Grace Holland
Regulatory Specialists, Inc.
3722 Ave. Sausalito
Irvine, CA 92606
Phone: 949-262-0411
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Email: grace@regulatoryspecialists.com

Classification

Class:	II (Two)
Procode:	KNT
CFR Reference:	876.5980

Device Description

The EntraCare Skin Level Gastrostomy Tube Kit (ECSL) is used as a replacement tube in an established stoma tract for patients who cannot consume an adequate diet orally.

The kit consists of:

Gastrostomy Tube

Elbow Connector Extension Set
Bolus Connector Extension set
Stoma Measuring Device
Universal Adapter Subassembly

Items within the kit that are supplied by an outside source:

35 ml Catheter Tipped Syringe
6 ml Slip Luer Syringe
4" X 4" Gauze

Item sod separately

Stoma Measuring Device

The Gastrostomy Tube consists of a Feeding Port Valve Subassembly that contains a valve used to open the fluid pathway allowing enteral feeding solutions to enter into the stomach. An inflatable balloon at the distal end secures the tube in the stomach through a stoma. The Gastrostomy Tube size variations include 14-24 French sizes and 0.8-4.5 cm length sizes. There are two slightly different valve designs available, Version 1 and Version 2. The design concept for the Gastrostomy Tube valve Version 1 utilizes a specially designed rubber mechanism that opens the fluid pathway when a bolus or elbow connector is inserted into the device. This specially designed rubber valve will seal around the connectors preventing leakage and allow unrestricted access into the fluid pathway. When the connections are removed, the valve will reseal immediately preventing leakage of fluids.

The design concept for the Gastrostomy Tube valve Version 2 utilizes a specially designed silicone mechanism that opens the fluid pathway when a bolus or elbow connector is inserted into the device. This specially designed valve will seal around the connectors preventing leakage and allow unrestricted access into the fluid pathway.

The Gastrostomy Tube also consists of an Inflation Valve Subassembly that contains a valve and spring mechanism. When the syringe is inserted into the Inflation Valve Subassembly, the tip pushes against the valve, which compresses the spring and opens the fluid path to inflate the balloon.

The Skin Level Gastrostomy Tube Kit contains all delivery items (accessories) necessary for enteral feeding applications. The accessories provided in the kit are two Extension Sets; one that allows continuous feeding from a pump, and the other that allows feeding from a catheter tip syringe. Two syringes are supplied (which have either been previously cleared for marketing by the FDA or are pre amendment devices); the 6 ml syringe is used to inflate the balloon of the gastrostomy tube and the 35 ml catheter tip syringe is used for bolus feeding. Sterile gauze is provided for

absorbency. A universal luer adapter is included for mating connections that require a female luer.

Equivalent Legally Marketed Device

Mic-Key® "G" Low Profile Gastrostomy Tube submitted by Ballard Medical Products Inc., K993138.

Performance Standards

As of the present time there have been no Performance Standards promulgated for this specific device.

The product does meet the following industry standards:

- The Skin Level Gastrostomy Tube Kit (ECSL) is sterilized by ETO in conformance with ANSI/AAMI/ISO 11135:1994 Medical Devices Validation and Routine Control Of Ethylene Oxide Sterilization (ETO) and EN 550 Sterilization Standards.
- The device complies with ANSI/AAMI/ISO 10993-1:1997;Class VI Biocompatibility Standards Concerning Cytotoxicity, Sensitization, Intracutaneous, Systemic Toxicity, and Hemocompatibility.
- The device is packaged in accordance with the ANSI/AAMI/ISO 11607:1997, Packaging For Terminally Sterilized Devices Standard.

The product also meets the following:

- The Elbow and Bolus Connector when connected to the feeding port valve withstands 20 inch ounces of torque.
- The feeding port valve assembly bond to the skin level Gastrostomy Tube main body bond withstands 20 inch ounces of torque.
- The device functions after 120 inflation valve flexes at 45 degrees from center line.
- The Gastrostomy Tube is able to maintain an inflated balloon for up to seven days.
- The valve in the feeding port valve assembly withstands a low backpressure of 0.05 psig (3.5 cm H2O) after 360 insertions.
- The valve closes at a low backpressure of 0.22 psig (15 cm H2O) after 7 days of continuous insertion.
- The Gastrostomy Tube fluid pathway and related elbow and bolus connections withstands a positive pressure of 15 psig after 360 insertions.

- The Gastrostomy Tube fluid pathway and related elbow and bolus connections withstands a positive pressure of 15 psig after 7 days of continuous insertion.
- The device is labeled in accordance with federal regulations.
- The device is Latex free.
- The Materials used to fabricate the Skin Level Gastrostomy Tube are of FDA cleared medical grade materials.
- Acid balloon test

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 31 2004

EntraCare, Inc.
c/o Ms. Grace Holland
Consultant
Regulatory Specialists, Inc.
3722 Ave. Sausalito
IRVINE CA 92606

Re: K041034
Trade/Device Name: Skin Level Gastrostomy Tube Kit
Regulation Number: 21 CFR §876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: 78 KNT
Dated: June 30, 2004
Received: July 1, 2004

Dear Ms. Holland:

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). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note:* If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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 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 (21 CFR Part 807); 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 the labeling regulation, please contact the Office of Compliance at (301) 594-4616. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR Part 807.97). 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) 443-6597, or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.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

510(k) Number (if known): K041034

Device Name: EntraCare Skin Level Gastrostomy Tube Kit (ECSL)

Indications For Use:

The ECSL is a low profile balloon gastrostomy tube indicated for use as a replacement tube in an established stoma tract for pediatric, adult and elderly patients who cannot consume an adequate diet orally. Gastrostomy feeding may be indicated for patients with a functioning gut who require long term feeding support. This may include patients for whom malnutrition already exists or may result, secondary to neurological diseases resulting in an abnormality in swallowing; tumors of the head, neck or esophagus; or upper airway diseases or oropharyngeal trauma resulting in an abnormality in swallowing. Some patients who require chronic use of supplemental fluids are also candidates for gastrostomy tube use.

(PLEASE DO NOT WRITE BELOW THIS LINE–CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041034