



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room W-066-0609  
Silver Spring, MD 20993-0002

Ms. Susan Curry  
Director of QA/QC & Regulatory Compliance  
EntraCare, LLC  
11315 Strang Line Road  
LENEXA KS 66215

OCT 23 2009

Re: K092418  
Trade/Device Name: EntraCare Gastrostomy Feeding Tube  
Regulation Number: 21 CFR §876.5980  
Regulation Name: Gastrointestinal tube and accessories  
Regulatory Class: II  
Product Code: KNT  
Dated: August 5, 2009  
Received: August 6, 2009

Dear Ms. Curry:

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 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.

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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, Director (Acting)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

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INDICATIONS FOR USE STATEMENT

The statement of Indications for Use for the Gastrostomy Tube, in compliance with 21 CFR 807.87(e), is provided below:

**Applicant:** EntraCare LLC

**Device Name:** EntraCare Gastrostomy Feeding Tube

**Indications For Use:**

The EntraCare Gastrostomy Feeding Tube is indicated for use as a replacement gastrostomy tube in an established stoma tract for patients who cannot consume an adequate diet orally. Gastrostomy feeding may be indicated for patients with a functioning stomach who require long term feeding support.

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

Concurrence of CD RH, Office of Device Evaluation (ODE)

  
(Division Sign-off)

Division of Reproductive, Abdominal and  
Radiological Devices

510(k) Number K092418

(Per 21 CFR 801.109)