



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAY 20 2003

Mr. Daniel Hamilton  
Manager, Device Regulatory Affairs  
Ross Products Division-Abbott Laboratories  
625 Cleveland Avenue  
Columbus, Ohio 43215-1724

Re: K031407  
Trade/Device Name: Ross Embrace Enteral Pump  
Regulation Number: 21 CFR 880.5725  
Regulation Name: Infusion Pump  
Regulatory Class: II  
Product Code: LZH  
Dated: May 2, 2003  
Received: May 5, 2003

Dear Mr. Hamilton:

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 Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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,



Susan Runner, DDS, MA  
Interim Director  
Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

VIII. INDICATIONS FOR USE

The Ross Embrace Enteral Pump is intended to control the delivery rate of liquid enteral feeding formulas to adult and pediatric patients requiring long- or short-term enteral nutrition support in hospitals, long term care facilities or homecare settings. The device is intended to deliver standard liquid enteral formulas or reconstituted powdered formulas that have been thoroughly mixed into solution. This device is not labeled or intended for parenteral use.

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use   ✓   OR Over-The-Counter Use \_\_\_\_\_

(Per 21 CFR 801.109)



(Division Sign-Off)  
Division of Anesthesiology, General Hospital,  
Infection Control, Dental Devices

510(k) Number:   K031407