K981541

AUG 13 1998

SUMMARY OF SAFETY and EFFECTIVENESS FOR THE CLEAR STAR PUMP

The ClearStar pump raises no new questions of safety or effectiveness above those currently associated with enteral feeding pumps. The operator's manual for the ClearStar pump provides warnings regarding volume sensitive patients similar to those found in the operating manuals of the Companion and Quantum enteral feeding pumps.

The pump's automatic clog clearing function has been designed to ensure that the nominal pressure exerted on a clog is in the 26 to 30 psi range. Additionally, to ensure that the patient is not underfed, the pump, if unsuccessful in clearing a clog before ten (10) minutes have elapsed, will alarm occlusion. Finally, the pump can only be in the clog clearing mode a maximum of twenty (20) minutes or ten times in any consecutive four (4) hour period. If twenty (20) minutes or ten times are exceeded, the pump will alarm occlusion.

Product literature for enteral feeding tubes (nasogastric and gastrostomy) cautions not to use a pump or syringe that causes pressures to build beyond 40 psi This warning is present as pressures above 40 psi can cause med-port plugs to separate and/or separation of the feeding set from the feeding tube. Pressure build-up with the ClearStar pump during occlusion is maintained safely below the maximum pressure specification of the feeding tubes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 13 1998

Mr. J. Paul Hanson
Vice President
Metabolic & Diagnostic Division
Frantz Medical
7740 Metric Drive
Mentor, Ohio 44060

Re: K981541
Trade Name: ClearStar Enteral Nutrition Pump
Regulatory Class: II
Product Code: LZA
Dated: June 4, 1998
Received: June 5, 1998

Dear Mr. Hanson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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. 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of

the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

S. Gutman for

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K981541

Device Name: ClearStar Enteral Nutrition Pump

Indications For Use:

The ClearStar pump can be used for adult and pediatric patients provided the patients can tolerate a feeding range within the pump operational specifications. Those specifications are:

- ❖ The flow rate range is 1-300 mL/hr in 1 mL/hr increments
- ❖ The flow rate accuracy is ± 10% or ± 0.5 mL/hr, whichever is greater
- ❖ The occlusion pressure limit is 26-30 psi.

If these specifications are not appropriate for a given patient, the ClearStar pump should not be used.

Precautions

All enteral pumps have the potential to bolus-feed or over deliver, which is an important consideration in feeding volume-sensitive patients. In these patients, a volume of product no more than four times the hourly feeding rate should be hung.

Confirm proper placement and function.

Confirm proper placement and function of patient's enteral feeding tube (nasogastric, jejunostomy, gastrostomy, etc.), and verify the following before initiating feeding:

1. A ClearStar Pump Set is being used.
2. Cassette is properly seated in pump.
3. When on AC power, pump is fully seated in charger.
4. Flow rate is set at the prescribed mL/hr.
5. Pump dial is turned to RUN.

Note: The Power Supply Cord is the DISCONNECT DEVICE.

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 Dental, Infection Control,
and General Hospital Devices

510(k) Number K981541

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use____

(Optional Format 1-2-96)