JUN - 1 2001

K011587

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Establishment

ENTRACON CORPORATION
22 WINDSOR DR.
FOXBOROUGH, MA 02035

Contact Person

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telephone 888 369 3644
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Date

May 9, 2001

Device Tradename – SENTINEL™ Enteral Feeding Pump
LH2001 Enteral Feeding Pump

Common name - Enteral Feeding Pump

Classification name - Infusion Pump, Enteral per 21CFR 880.5725

Classification - Class II

Predicate devices

This device is substantially equivalent to devices previously cleared for interstate commerce by the FDA 510(k) process. Two such devices are the KM60 reviewed under control number K852965 (08/21/1985) and the Compat-235 / -240 reviewed under control number K940555 (02/01/1995). There are no new concerns relative to pump safety or efficacy.

Device description

The SENTINEL / LH2001 is a peristaltic pump intended for controlled delivery of liquid nutrients. The pump requires cleared disposable delivery tube sets approved by ENTRACON CORPORATION. The pump is used to feed hospital or long term care patients.

The microprocessor controlled pump operates while normally connected to a 120 VAC outlet. In the event of AC power loss, or when moving patients, the pump operates on an internal backup battery. The battery is always being charged by during AC power use. With a fully charged battery, the pump can operate for 12 hours at a set delivery rate of 125 ml/hr. The pumping mechanism is a rotor, driven by a stepper motor. The stepper motor runs at a constant speed with delivery rate dependent on on/off timing. The pump includes an integral pole clamp for securing it, typically to an IV pole.

Visual and auditory alarms warn of flow-related problem conditions; either occluded flow or excessive flow. Flow detection is accomplished by optically sensing falling drops of nutrient in the pump-mounted drip chamber. Additionally, other warning actions occur when liquid nutrient container is empty, when the pump has completed delivery of a preprogrammed dose, when the pump has been idle for more than 2½ minutes, or when, during battery operation, the battery requires recharging.

Performance Results

When tested at the extremes of flow rate, operating temperature and nutrient viscosity, and with the cleared-to-market disposable set, the SENTINEL / LH2001 enteral pump delivers within ±10% accuracy.

Additionally, the pump has been tested for electrical and fire hazard safety and conforms with the standard UL544. The pump has also been tested for electromagnetic compatibility per the standard EN60601-1-2.

Conclusion

Based on the above results, the pump has been proven to be safe and effective.

Substantial Equivalence

Based on comparison of the intended use and the principles of operation of the predicate devices, the intended use and the principles of operation of the SENTINEL / LH2001 enteral feeding pump has been shown to be substantially equivalent and are detailed in the table below.

SUBSTANTIAL EQUIVALENCE COMPARISON

FEATURE	EMPIRE (KMI) KM-60	SANDOZ COMPAT –235/-240	ENTRACON SENTINEL
510(k) clearance	K852965	K940555	this submission
Intended Use	Enteral Feeding	Enteral Feeding	Enteral Feeding
Pump Type	Peristaltic	Peristaltic	Peristaltic
Mode of Action	Tubing in tension against rotor	Tubing in tension against rotor	Tubing in tension against rotor
Safety Standard	UL544	UL544	UL544
Electromagnetic compatibility	No	No	IEC 601-1-1-2 sec (2)
Hospital and Home Use	Yes	Yes	Yes
Pump Weight	5.6 pounds	5.7 pounds	5.2 pounds
Pump Size	7.4" H x 9.0" W x 5.1"D	7.4" H x 9.5" W x 5.3"D	7.5" H x 9.0" W x 5.2"D
Enclosure	Flame Retarded Plastic	Flame Retarded Plastic	Flame Retarded Plastic
Pole Clamp Mountable	Yes	Yes	Yes
Power Requirement	120VAC, 0.25amp, 60Hz	115VAC, 0.19amp, 60Hz	120VAC, ⅛amp, 60Hz
Battery	Sealed Lead-Acid	Sealed Lead-Acid	Sealed Lead-Acid
Battery Recharge Time	12 hr	12 hr	10 hr
Battery Operating Time	2 hr @ 125 ml/hr	8 hr @ 100 ml/hr	12 hr @ 125 ml/hr
Battery Operation Indicator	Yes	Yes	Yes
Low Battery Indicator / Alarm	Yes	Yes	Yes
Numeric Display, Rate	3-digit LED	3-digit LED	3-digit LED
Delivery Rate	1-50 ml/hr @1 ml/hr increments 50-295 ml/hr @5ml/hr increments	1 -295 ml/hr @ 1 ml/hr increments	5 -295 ml/hr @ 1 ml/hr increments
Accuracy, Delivery	± 10% of selected rate	± 10% of selected rate	± 10% of selected rate
Numeric Display, Dose	4-digit LED	4-digit LED	4-digit LED
Accumulated Dose Display Option	No	Yes	Yes
Dose Limit	No	adjustable 0-9995 ml in 5 ml increments	adjustable 1-2000 ml in 1 ml increments; and 2000-9999 ml in 5 ml increments
Dose Complete Indicator / Alarm	No	Yes	Yes
Occlusion/Empty Indicator / Alarm	Yes	Yes	Yes
Dose / Rate Settings Retained in Memory	No	Yes	Yes
Occlusion Pressure	25 psi maximum	15 psi maximum	15 psi maximum
Flow Monitoring	No	Yes	Yes
Free Flow Indicator / Alarm	No	Yes	Yes
Flow Sensing Means	Drip Chamber	Drip Chamber	Drip Chamber
Administration Set	Disposable	Disposable	Disposable (K862489)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 1 2001

Entracon Corporation
C/O Mr. Donald J. Sherratt
Responsible Third Party Official
Intertek Testing Services
70 Codman Hill Road
Boxborough, Massachusetts 01779

Re: K011587
Trade/Device Name: Sentinel Enteral Feeding Pump,
LH2001 Enteral Feeding Pump
Regulation Number: 880.5725
Regulatory Class: II
Product Code: LZH
Dated: May 21, 2001
Received: May 23, 2001

Dear Mr. Sherratt:

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 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. 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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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" (21CFR 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/dsma/dsmamain.html".

Sincerely yours,

Susan Runner

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

Con

Indications for use statement

510(k) Number (if known): -

Device Name: External Enteral Infusion Pump

Indications For Use:

The enteral feeding pump accurately controls the flow of liquid feeding solution to patients who are unable or unwilling to consume adequate nutrients. Liquid feedings may consist of commercially prepared formulas or blenderized foods and are most often delivered by means of nasogastric, nasoduodenal of nasojenjunal feeding tubes. In some cases a surgically placed esophagostomy, gastrostomy or enterostomy tube may be used.

The pump is not intended for use with blood or blood products. The pump is not for intravenous delivery.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Patricia Cucente

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K011587

Prescription use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)