K993797

JAN 20 2000

Appendix C

510(k) Summary
Enthermics Medical Systems
EC-770l Fluid Warming Cabinet

I. General Information on Submitter:

Name: Enthermics Medical Systems
Address: W164 N9221 Water Street
Menomonee Falls, WI 53052-0450
Telephone: (262) 251-8356
Fax: (262) 251-7067
Name of Contact Person: Mr. Mark Suszkowski

Date Summary Prepared: November 5, 1999

II. General Information on the Device

Name: EC-770l Fluid Warming Cabinet

Classification Name: LHC, Warmer, Irrigation Solution
LGZ, Warmer, Thermal, Infusion Fluid

III. Predicate Devices: TempO II™ Warming Cabinet
Castle® 5500 Series Warming Cabinets
AMSCO Warming Cabinets

IV. Description of the Device:

The EC-770l is a stainless steel fluid warming cabinet that utilizes a fully insulated electrothermal cable array that is wrapped inside the bottom and two sides of the cabinet to provide uniform radiant, conductive and convective heating. The device can be used to heat irrigation fluids to a temperature ranging from 90°F to 150°F, or injection fluids to a range of 90°F to 110°F. The device also contains an over-temperature alarm which provides an audible and visual alarm when the internal temperature reaches 10°F above the selected temperature.

V. Intended Use:

The Enthermics Medical Systems EC-770l Fluid Warming Cabinet is designed to safely store and warm irrigation fluids or injection fluids in accordance with the recommended warming temperatures and storage times stated in the fluid manufacturers' labeling.

VI. Technological Characteristics of Device Compared to Predicate Device:

The EC-770l is nearly identical to the three predicate devices in all material respects. All four devices use the same basic technology (non-electromagnetic heating) and utilize similar over-temperature alarm systems (audible and visual indicators). The only material difference between the EC-770l and the predicate devices is the selectable modes of operation (irrigation or injection) on the EC-770l. The selectable modes, however, do not raise additional questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 20 2000

Emalee G. Murphy, Esquire
McKenna & Cuneo, L.L.P.
Attorneys at Law
1900 K Street N.W.
Washington, D.C. 20006-1108

Re: K993797
Trade Name: Enthermics Medical Systems EC-7701 Fluid Warming Cabinet
Regulatory Class: I
Product Code: LDQ
Dated: November 8, 1999
Received: November 9, 1999

Dear Ms. Murphy:

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,

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

Enclosure

Indications for Use Statement

510(k) Number:

Device Name: EC-7701 Fluid Warming Cabinet

Indications For Use:

The Enthermics Medical Systems EC-7701 Fluid Warming Cabinet is designed to safely store and warm irrigation fluids or injection fluids in accordance with the recommended warming temperatures and storage times stated in the fluid manufacturers' labeling.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use ✓
(Per 21 C.F.R. § 801.109)

Patricia Cinconte
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K995777