

Section 2: 510(k) Summary

General Information

Submitter Name and Address: **HemoCleanse, Inc.**
2700 Kent Avenue
West Lafayette, IN 47906

Contact: **Stephen R. Ash, MD, FACP**
Chairman, Director of R&D
(765) 463-9540

510(k) Summary Preparation Date: **September 30, 1999**

Device Trade Name: **ThermoChem-HT System**

Device Common Name: **Thermal Infusion Fluid Warmer (80LGZ)**

Device Classification Name: **Unclassified**

Predicate Devices

The ThermoChem-HT System incorporates the following components used in legally marketed cardiopulmonary bypass systems and peritoneal dialysis systems to circulate warmed fluids: internal water heater/cooler, a roller-type fluid pump, inputs for monitoring temperature, and a disposable circuit with an integral heat exchanger, fluid reservoir, and tubing connectors. The system also includes computer record storage and a touch screen that directs the user through set-up and use.

Device Description

The principal components, features and functions of the ThermoChem-HT System include an internal water heater/cooler, roller-type fluid pump, inputs for monitoring temperature, touch screen to direct the user through set-up and use, computer record storage, and disposable circuit that includes an integrated heat exchanger, fluid reservoir, and tubing connectors. The user provides and places commercially available introduction and drainage catheters into the patient's peritoneal cavity. One catheter acts as an Inlet and the other as an Outlet. The user also provides the Lactated Ringer's Solution, U.S.P., or another physiologically compatible sterile solution that is circulated into and out of the peritoneal cavity.

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The system heats Lactated Ringer's Solution, U.S.P., or another physiologically compatible sterile solution, and circulates it into and out of the peritoneal cavity. Flow from the patient Outlet Catheter gravity drains into a fluid reservoir, then through to a roller Pump and then to an inline, disposable Heat Exchanger. The Heat Exchanger is interfaced with heated water from a heater/cooler that provides regulated temperature control to the Heat Exchanger. The heated solution then passes to the peritoneal cavity through the Inlet Catheter. The inline reservoir also aids in priming the disposable circuit and maintaining adequate fluid volumes. The system monitors the temperature of the circulating Lactated Ringer's Solution, U.S.P., or another physiologically compatible sterile solution.

Intended Use

The intended use of the ThermoChem-HT System is to raise the core temperature of the peritoneum to the desired targeted temperature by continuously lavaging the peritoneum with circulating warmed Lactated Ringer's Solution, U.S.P., or another physiologically compatible sterile solution.

Laboratory/Clinical Tests

The major components of the ThermoChem-HT™ System are legally marketed devices used in either cardiopulmonary bypass systems or peritoneal dialysis systems to circulate warmed fluids. The manufacturers' 510(k) submissions have established the performance, biocompatibility, electrical safety, and electromagnetic compatibility, as appropriate, for these components. HemoCleanse, Inc. also provided similar information for the ThermoChem-HT™ System. In addition, HemoCleanse, Inc. provided software verification and validation information and published clinical studies involving intra-peritoneal perfusion hyperthermia that demonstrated the safety of the recommended temperature for the intended use of the ThermoChem-HT™ System.

Conclusions

The ThermoChem-HT™ System is substantially equivalent to legally marketed devices intended to circulate warmed fluids through the peritoneal cavity.



DEC 30 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Stephen R. Ash, M.D., FACP
Chairman, Director of R&D
HemoCleanse, Inc.
2700 Kent Avenue
West Lafayette, IN 47906

RE: K993330
ThermoChem-HT System Thermal
Infusion Fluid Warmer
Dated: November 2, 1999
Received: November 3, 1999
Regulatory Class: II
21 CFR 876.5630/Procode: 78 MLW

Dear Dr. Ash:

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) 594-4613. 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/dsma/dsmamain.html>".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K993330

Device Name: ThermoChem-HT

Indications For Use:

The intended use of the ThermoChem-HT System is to raise the core temperature of the peritoneum to the desired target temperature by continuously lavaging the peritoneum with circulating warmed Lactated Ringers's Solution, U.S.P., or another physiologically compatible sterile solution.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K993330

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____