MAR - 4 2010

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510(k) Summary

Model **TTS100** Portable Hyperthermic Perfusion Device

510(k) Number: K092366

Submitted in accordance with the requirements of SMDA 1990 and 21CFR807.92.

1.0 21CFR 807.92(A)(1)

1.1 Applicant's Information

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1.2 Submitter's Information

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1.3 Date

March 1, 2010

2.0 21CFR 807.92(A)(2)

2.1 Device Information

Trade/Proprietary Name: TTS100 Portable Hyperthermic Perfusion Device
Common Name: **TTS100** Portable Hyperthermic Perfusion Device
Model Number: **TTS100**
Regulation Number: None
Regulation Name: None
Regulatory Class: Unclassified, pre-amendment device; non-exempt from 510(k)
Device Classification Name: Warmer, thermal, Infusion fluid
Classification Panel: General Hospital
Classification Product Code(s): LGZ

2.2 Device Classification

Infusion fluid thermal warmers and their accessories are unclassified, Pre-Amendment devices. 510(k) premarket notification submissions for these devices are reviewed by the General Hospital Devices Branch, Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices.

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3.0 21CFR 807.92(a)(3)

3.1 Predicate Device Information

Predicate Devices			
510(k) #	Device	510(k) Sponsor	510(k) Clearance Date
K993330	ThermoChem-HT System	Hemocleanse, Inc.	12/30/1999
K070654	Belmont Hyperthermia Pump	Belmont Instrument, Inc.	6/8/2007

4.0 21CFR 807.92(a)(4)

4.1 Device Description

The **TTS100** Portable Hyperthermic Perfusion Device is a prescription device comprised of two components - one durable and one disposable. The TTS100 Console is the durable component - a portable, reusable unit containing heater, pump, user touchscreen, microprocessor, and interface electronics. The primary user interface of the **TTS100** is a large, color touchscreen display that receives operational commands from the clinical user, and presents normal and abnormal operating conditions, flow rate, output fluid temperature, patient temperature, target temperature, line pressure, alarm and status messages, various timers and auxiliary temperatures. The TTS100 software monitors various sensors in the fluid path to ensure safe operation, automatically reacts to unsafe conditions, and alerts the clinical user to those conditions for resolution. Independent protection circuits prevent unsafe operation in the event of system software fault.

The disposable, single-use component is the Hyperthermic Lavage Tubing Set, which has two sub-components - a Circulation Loop and an Accessory Kit. The Circulation Loop contains the filtered soft-shell fluid reservoir, inlet ports, vent lines, integrated distributed sensors, patient inlet circulation loop tubing, patient outlet circulation loop tubing, and drain line. The Accessory Kit - an integral component of the Hyperthermic Lavage Tubing Set - contains patient inlet and patient outlet tubing, tubing connectors, and auxiliary temperature sensors. Portions of the Accessory Kit can be implanted into the patient for use during the lavage procedure. The Circulation Loop does not have direct patient contact - only the circulating fluid within the loop contacts the patient. The Hyperthermic Lavage Tubing set is designed such that fluid travels through the Disposable Set without wetting the heater, pump or other TTS system components (e.g., only the internal surfaces of the Disposable Set are wetted), enabling rapid and straightforward post-processing of the TTS100 Console between patients. The Hyperthermic Lavage Tubing Set is supplied sterile, packaged in a proprietary-design container, and is only intended to be used in conjunction with the **TTS100** Portable Hyperthermic Perfusion Device.

5.0 21CFR 807.92(a)(5)

5.1 Indications for Use

The intended use of the **TTS100** Portable Hyperthermic Perfusion Device is to raise the temperature of the thoracic or peritoneal cavity to the desired target temperature by continuously lavaging the cavity with circulating, warmed, physiologically compatible sterile solution, according to a protocol to be selected by the physician.

6.0 21CFR 807.92(a)(6)

6.1 Technological Characteristics Comparison to Predicate Device(s)

As compared to the predicate devices, the **TTS100** Portable Hyperthermic Perfusion Device has the same operating principle, energy type, environmental specifications, and performance specifications. All devices use a roller-type fluid pump, touchscreen-based clinical user interface for machine set-up and control, sensor monitoring of various fluid temperatures, and a proprietary-design disposable set including large fluid reservoir to circulate sterile fluid into and out of the body cavity. For the **TTS100**, fluid in the reservoir is heated via direct heat to the desired temperature, and the heater drain tubing passes through a roller pump and out to the patient inlet. Fluid returns from the patient outlet via gravity drain back to the fluid reservoir. The **TTS100** monitors circulating fluid temperature and pressure, and automatically responds to ineffective or unsafe operating conditions.

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7.0 21CFR 807.92(b)(1)

7.1 Performance Data - Discussion of Non-Clinical Tests

7.1.1 FDA Recognized Consensus Standards

The **TTS100** is designed to, complies with, and has been tested as part of verification and validation activities to, the FDA Recognized Consensus Standards listed in the table below, as applicable to device features and components:

Requirement	Test Method (FDA Recognized Consensus Standard) Reference #	Title
Biocompatibility	AAMI/ANSI/ISO 10993-1:2003(E)	Biological evaluation of medical devices - Part 1: Evaluation and testing
	AAMI/ANSI/ISO 10993-5:1999	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
	AAMI / ANSI / ISO 10993-7:1995(R)2001	Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals.
	AAMI/ANSI/ISO 10993-10:2002	Biological evaluation of medical devices - Part 10: tests for irritation and delayed-type hypersensitization
	AAMI/ANSI/ISO 10993-11:2006	Biological evaluation of medical devices - Part 11: Tests for systematic toxicity
Electrical Safety, EMC	IEC 60601-1:1988+A1:1991+A2:1995 (IEC 60601-1+A1+A2)	Medical electrical equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995
	IEC 60601-1-2:2001+A1:2004 (IEC 60601-1-2+A1)	Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests (Ed. 2.1)
Sterility	AAMI / ANSI / ISO 11135-1:2007	Sterilization of health care products - Ethylene oxide - Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices.
Packaging	ASTM D4169-05:2005	Standard Practice for Performance Testing of Shipping Containers and Systems

7.1.2 Software Verification/Validation Testing

As part of software verification/validation activities, and in support of substantial equivalence, the following tests were carried out the **TTS100** to evaluate its ability to meet product performance specifications. Specifically, the **TTS100** was tested to assess...

- The ability of the **TTS100** to heat fluids over the full range of fluid flowrates.
- The ability of the **TTS100** to maintain fluid temperature over the full range of fluid flowrates.
- The ability of the **TTS100** to detect and automatically respond to unsafe or ineffective operating conditions, as caused by the failure of the system sensors, excessive fluid temperature, excessive fluid pressure, or system-internal component failures.
- The ability of the **TTS100** to inform the clinical user of those unsafe or ineffective operating conditions via notifications, alerts, alarms, and/or system faults.
- The ability of the **TTS100** to mitigate against known or predictable operator errors.
- The ability of the **TTS100** to store treatment parameters and data in non-volatile memory.
- Measured temperature accuracy over the full range of fluid flowrates within the operating pressure range.
- Measured pressure accuracy over the full range of fluid flowrates within the operating temperature range.
- Fluid flowrate accuracy over the full range of fluid flowrates within the operating temperature and pressure range.

The **TTS100** performed within specification in all of the above tests.

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7.1.3 Human Factors

A human factors non-clinical study evaluated user- and patient-safety risks associated with the design of the **TTS100**, and demonstrated that the task-risks have been identified, addressed and mitigated.

8.0 21CFR 807.92(b)(2)

8.1 Performance Data - Discussion of Clinical Tests

N/A

9.0 21CFR 807.92(b)(3)

9.1 Conclusions

Based upon safety and performance testing and compliance with voluntary standards, ThermalTherapeutic Systems, Inc. believes that the **TTS100** Portable Hyperthermic Perfusion Device is substantially equivalent to the predicate devices, and does not raise any new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Thermal Therapeutic Systems, Incorporated
C/O Mr. James Jochen Rogers
General Manager
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Moon Township, Pennsylvania 15108

JAN 1 0 2017

Re: K092366
Trade/Device Name: TTS100 Portable Hyperthermic Perfusion Device
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: LGZ
Dated: March 3, 2010
Received: March 4, 2010

Dear Mr. Rogers:

This letter corrects our substantially equivalent letter of March 4, 2010.

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K092366

Indications for Use

510(k) Number (if known): K092366

Device Name: TTS100 Portable Hyperthermic Perfusion Device

Indications For Use:

The intended use of the TTS100 Portable Hyperthermic Perfusion Device is to raise the temperature of the thoracic or peritoneal cavity to the desired target temperature by continuously lavaging the cavity with circulating, warmed, physiologically compatible sterile solution, according to a protocol to be selected by the physician.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(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 Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K092366