May 5, 2025

ThermaSolutions, LLC
℅ Jessica Czamanski
Regulatory, Quality & Compliance Consultant
DuVal & Associates, P.A.
Suite 1820, Medical Arts Building
825 Nicollet Mall
Minneapolis, Minnesota 55402

Re: K240447
Trade/Device Name: ThermoChem HT-2000 System and Intraperitoneal Hyperthermia (IPH) Procedure Kit (HT-2000)
Regulation Number: 21 CFR 876.5630
Regulation Name: Peritoneal dialysis system and accessories
Regulatory Class: Class II
Product Code: MLW
Dated: March 5, 2025
Received: March 6, 2025

Dear Jessica Czamanski:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-

devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Maura Rooney -S

Maura Rooney
Assistant Director
DHT3A: Division of Renal, Gastrointestinal, Obesity, and Transplant Devices
OHT3: Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240447

Device Name

ThermoChem HT-2000 System and Intraperitoneal Hyperthermia (IPH) Procedure Kit (HT-2000)

Indications for Use *(Describe)*

The intended use of the ThermoChem HT-2000 System is to raise the core temperature of the peritoneum to a desired target temperature, in patients who require warming, including oncology patients, by continuously lavaging with circulated and warmed Lactated Ringer's Solution, U.S.P., or other physician specified fluids.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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K240447 – 510(k) Summary

I. Submitter

Submitter Name:	ThermaSolutions LLC
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Date of Preparation:	May 5th, 2025

II. Application Correspondent

Contact's Name:	DuVal & Associates, P. A.
Contact Person:	Jessica Czamanski
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	Minneapolis MN 55402
	United States
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III. Device

Trade Name:	ThermoChem HT-2000 System and Intraperitoneal Hyperthermia (IPH) Procedure Kit (HT-2000)
Common Name:	Peritoneal dialysis system and accessories
Classification Name:	Warmer, Peritoneal Dialysate
Product Classification:	Class II
Regulation Number:	21 CFR 876.5630
Product Code:	MLW

IV. Predicate Device

Manufacturer:	ThermaSolutions LLC
Device Name:	ThermoChem HT-2000

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510(k) Number:	K131583
Product Classification:	Class II
Regulation Number:	21 CFR 876.5630
Product Code:	MLW

V. Device Description

The ThermoChem HT-2000 System is composed of the ThermoChem Unit and touchscreen monitor, and the Intraperitoneal Hyperthermia (IPH) Procedure Kit. The ThermoChem HT-2000 and IPH Procedure pack are used to raise the core temperature of the peritoneum to a desired target temperature by continuously lavaging the peritoneum with circulating and warmed sterile solution. The ThermoChem unit and monitor are reusable components of the system. The IPH Procedure kit consists of an array of sterile, single-use, disposable components. The touchscreen monitor on the ThermoChem unit provides for the user interface with the ThermoChem system. The touch screen can be used to control the main functions of the system. The ThermoChem HT-2000 System is comprised of the same hardware as the predicate K31583 device.

The ThermoChem HT-2000 is a tool for the heating and circulation of fluid. Physicians are responsible for selecting the fluids used and the therapy delivered. Oncology patients, undergoing a temperature-targeted warming of the peritoneum with continuous circulation and lavage, may be subject to physician specified fluids for therapies such as continuous hyperthermic peritoneal perfusion. There are no known drugs, other than Lactated Ringer's Solution, U.S.P., specifically approved for these therapies.

VI. Intended Use/Indications for Use

The intended use of the ThermoChem HT-2000 System is to raise the core temperature of the peritoneum to a desired target temperature, in patients who require warming, including oncology patients, by continuously lavaging with circulated and warmed Lactated Ringer's Solution, U.S.P., or other physician specified fluids.

VII. Indications for Use Comparison

The proposed indications for use clarify that the patient population includes oncology patients and that the clinical has the responsibility to specify which fluids other than Lactated Ringer's should be used with the device, adding specificity to the indications for use under the device's general intended use.

VIII. Comparison of Technological Characteristics

The subject ThermoChem System has not undergone any significant changes in materials, design, energy source, or other features compared to the K131583 clearance. The only change that is the

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subject of this 510(k) is the indication for use change which does not result in a change to the previously cleared intended use.

IX. Performance Testing – Bench

All performance data included in K131583 for the predicate ThermoChem HT-2000, also supports the proposed device.

Performance Testing – Animal

This submission does not include any animal performance testing. It was determined that no such testing is required to demonstrate substantial equivalence.

Performance Testing – Clinical

This submission does not include any clinical performance testing. It was determined that no such testing is required to demonstrate substantial equivalence.

X. Conclusion

The proposed ThermoChem HT-2000 has the same intended use, operating principle, fundamental technology, materials, and manufacturing as the predicate device. The difference in indications for use, clarifies the patient population for which the device is intended which is the same population that the predicate device has been used on since its clearance. These differences in indications for use do not introduce new questions for safety and effectiveness. The information provided in this submission demonstrated that the subject device, ThermoChem HT-2000, is substantially equivalent to its predicate, ThermoChem HT-2000 K131583.