ThermaSolutions LLC
Rhea Johny
Regulatory Specialist
1889 Buerkle Road
St. Paul, Minnesota 55110

December 6, 2022

Re: K222575
Trade/Device Name: HurriChem Device Kit
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: November 9, 2022
Received: November 9, 2022

Dear Rhea Johny:

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. 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 located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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 Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for

devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Colin K. Chen -S

for

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

Device Name
HurriChem Device Kit

Indications for Use *(Describe)*
The ThermaSolutions HurriChem Device Kit is indicated for use in patients undergoing a laparoscopic procedure. It is designed to deliver sterile irrigation fluids to surgical sites during laparoscopic procedures and to lavage blood and tissue debris from the surgical site.

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.

510(k) Summary for the HurriChem Device Kit

Contact Information

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Rhea Johny, Regulatory Specialist

4 March 2022

Information about the Device

Trade name: HurriChem Device Kit

Common name: laparoscopic irrigation

Classification name: Endoscope and accessories (21 CFR 876.1500, Product Code GCJ)

Substantially Equivalent Device

Legally marketed device: DANNIK Laparoscopic Suction Irrigation System (K192643)

Common name: laparoscopic irrigation

Classification name: Endoscope and accessories (21 CFR 876.1500, Product Code GCJ)

Indication for Use

The ThermaSolutions HurriChem Device Kit is indicated for use in patients undergoing a laparoscopic procedure. It is designed to deliver sterile irrigation fluids to surgical sites during laparoscopic procedures and to lavage blood and tissue debris from the surgical site.

Description of the Device

ThermaSolutions' HurriChem Device Kit consists of the HurriChem Irrigation Wand and braided poly tubing. The HurriChem Device Kit is intended for use to deliver sterile irrigation fluids to surgical sites during laparoscopic procedures. It is designed to lavage blood and tissue debris from the surgical site. The kit is to be used in conjunction with standard injection pumps. The kit is to be used only by physicians trained in the use of this device. The device is packaged and sterilized for single use only, and should be discarded after use according to the policy of the facility.

The HurriChem Device Kit consists of a stainless-steel wand and a length of braided poly tubing. The one end of the tubing attaches to the stainless-steel wand, and the other end of the tubing is intended to attach to a standard injection pump (not part of the device). The sterile fluid is delivered from the injection pump through the poly tubing and into the stainless-steel wand. The wand has internal mechanics that deliver the fluid as microscopic droplets in a fine mist. The irrigation using fluid droplets allows for maximum lavage of the area with a minimal amount of fluid.

Technological Characteristics of HurriChem Compared to Predicate Device

	HurriChem	DANNIK
Intended use:	Laparoscopic surgery	Same
Insertion via trocar:	Yes	Yes
Sterilization:	Ethylene Oxide	Same
Prescription only:	Yes	Yes

Disposable:	Yes	Yes
Single use:	Yes	Yes
Biocompatibility	Yes	Yes
Electrosurgery capable:	No	No
Suction capable:	No	Yes
Fluid delivered by external pump source:	Yes, not part of device	Yes, not part of device
	Materials	
wand/probe:	Stainless steel	Same
tubing:	Braided polyurethane	PVC
hand piece w/valve:	None	Polycarbonate

Summary of Technological Difference in Irrigation Droplet Size

Both devices receive irrigation fluid via delivery from an external mechanical source. The wand (HurriChem) or probe (DANNIK Suction Irrigation) directs the irrigation fluid as determined by the physician. The HurriChem delivers the irrigation as small droplets of fluid. The DANNIK Suction Irrigation delivers the irrigation as a larger stream of fluid.

The HurriChem device's mechanical conversion of the fluid into droplets permits a small volume of fluid to be used for irrigation. The stainless-steel wand in the HurriChem device kits contains a nozzle with a micro-opening because the small opening converts and delivers the irrigation fluid in the form of droplets. The Suction Irrigation has a larger opening that delivers the irrigation fluid as a stream of fluid.

Summary of Technological Difference in Suction

The HurriChem Device Kit is indicated for use to deliver sterile irrigation fluids to surgical sites during laparoscopic procedure. The device is not designed nor intended to provide suction or removal of fluid. Evacuation of fluid, if desired by the clinician, may be performed with laparoscopic suction or evacuation devices, drains or catheters.

Non-clinical Testing

A series of tests were performed to assess the safety and effectiveness of the HurriChem Device Kit to the predicate device. Biocompatibility, sterilization validation, packaging validation, shelf life and transportation testing were completed. Additionally, ThermaSolutions Engineering and Product Development teams evaluated fit, function, performance and equivalence of the device through a combination of human factors studies and bench testing. All the tests demonstrate that the device meets the requirements of its pre-defined acceptance criteria and intended use. The results of the non-clinical testing demonstrate that the HurriChem Device Kit is as safe and effective as the predicate device.

Clinical Testing

No clinical trials were performed on the HurriChem Device Kit.

Conclusion

The HurriChem Device Kit has the same intended use and application as the predicate device. The materials of the HurriChem Device Kit and the predicate device are equivalent. The difference in technical characteristics of the HurriChem's irrigation spray from DANNIK's irrigation stream does not raise different questions of safety and effectiveness. The non-clinical testing and performance evaluations show the ThermaSolutions HurriChem Device Kits is as safe and effective and meets the same expected performance as the DANNIK Suction Irrigation System. Therefore, the proposed HurriChem Device Kits is substantially equivalent to the predicate.