510(k) Summary

JUN 2 0 2014

Thermedx Fluid Management System
Thermedx, LLC

510(k) Submitter	Thermedx, LLC 31200 Solon Road, Unit #1 Solon, Ohio 44139
Contact Person	Douglas L. Carr *Phone:* (440) 542-0883 *Fax:* (440) 542-0920 *E-mail: Dcarr@thermedx.com*
Date Prepared	30 April 2014
Device Name	Proprietary Name: Thermedx Fluid Management System Common Name: Hysteroscopic Insufflator Regulation Number: 21 CFR § 884 1700 Regulatory Class: II Classification Name: HIG, LGZ, HRX
Intended Use	The Thermedx Fluid Management System is intended for irrigation and fluid warming in laparoscopic procedures, and distention, fluid warming, and volume/deficit measurements in endoscopic procedures within gynecology, urology, and orthopedic disciplines.
Device Description	The Thermedx device is a fluid management system intended for surgical applications. The device consists of a main unit and disposable tubing sets. A rolling stand-mounted device houses infrared fluid heating technology and a peristaltic fluid pump with closed-loop controls. The Thermedx monopolar electrocautery probes are an optional accessory for electrosurgical cutting and coagulation.
Technological Comparison	Thermedx Fluid Management System is identical to the previous version, with no technological differences. Packaging and sterilization means remain unchanged as well. Changes relate solely to the individual procedure settings and the addition of a high pressure disposable tubing set HLL003
Non Clinical Tests	Non clinical testing performed including the following. 1. Biological testing of tube-sets based on 10993-1:2009 including: a. Cytotoxicity using the MEM Elution Assay method (10993-5:2009) b. Sensitization using the Kligman or Buehler methods (10993-10:2010) c. Irritation using the Intracutaneous Reactivity/Irritation Test (10993-10:2010) 2. Software verification testing: Verify individual setting limits within table and regression testing via running range of simulated use cases. 3. Verify crack pressures of valve for HLL003 is within 240-360mmHg range.
Clinical Information	In support to the changes to the procedures and settings please refer to the numerous journal articles, practical guidelines, hospital guidelines.
Substantial Equivalence	The Thermedx Fluid Management System is substantially equivalent in terms of safety and effectiveness to the device as originally cleared, Thermedx 37~5 (K091939).

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

June 20, 2014

Thermedx LLC
Jeff B. Williams
Engineering Manager
31200 Solon Rd., Unit 1
Solon, OH 44139

Re: K133799
Trade/Device Name: Thermedx Fluid Management System
Regulation Number: 21 CFR 884.1700
Regulation Name: Hysteroscopic Insufflator
Regulatory Class: Class II
Product Code: HIG, LGZ, HRX
Dated: May 23, 2014
Received: May 27, 2014

Dear Jeff B. Williams,

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 (21CFR Part 807); labeling (21 CFR Part 801); 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 Part 801), 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 (21CFR 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,

Herbert P. Lerner -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number
K133799

Device Name
Thermedx Fluid Management System

Indications for Use
The Thermedx Fluid Management System is intended for irrigation and fluid warming in laparoscopic procedures, and distention, fluid warming, and volume/deficit measurements in endoscopic procedures within gynecology, urology, and orthopedic disciplines.

Type of Use

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

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH)

Herbert P. Lerner -S
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