

K091939

510(k) Summary

Traditional 510(k) Notification Thermedx 37~5™ Fluid Management System Thermedx, LLC

JUL 23 2010

Applicant

Thermedx, LLC
31200 Solon Rd. Unit#1, Solon Oh 44139
440-542-0883
Contact Person: Eng Mgr, Jeff Williams
Date Prepared: June 10, 2010

Device Name

Proprietary Name: Thermedx 37~5™ Fluid Management System
Common Name: Thermal infusion fluid warmer
Classification Name: Unclassified device (product code LGZ)

Substantial Equivalence

The Thermedx 37~5 is substantially equivalent in terms of safety and effectiveness to the following combination of predicate devices:

1. Fluido® Blood and Fluid Warmer (BK050058) and Fluido Accessories (BK 0700755), The Surgical Company International
2. Ranger® Irrigation Fluid Warming System (K060939), Arizant Healthcare Inc.
3. Level 1® NORMOFLO® Irrigation Fluid Warmer (K072080), Smiths Medical ASD, Inc.
4. Dolphin® II Fluid Management System (K011876), GyruS ACMI, Inc.
5. HydroFlex® Irrigation System AD/LI/HD, (K011876) Davol

Device Description

The Thermedx 37~5 is a general purpose fluid management system intended for standard surgical fluid management applications. The device consists of a Base 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 unit operates in 2 primary modes with fluid heating: flow control and pressure control. The Disposable Tubing Sets include IV bag spike, heating cartridge, and trumpet valve or luer lock connectors for endoscopes or other devices.

Intended Use

The 37~5 is a multi-purpose fluid management system indicated for the following:

- Laparoscopy: warming fluids for irrigation and aspiration
- Hysteroscopy: uterine distention during diagnostic and operative procedures
- Cystoscopy: distention of the bladder during diagnostic and operative procedures (with optional fluid warming)
- Arthroscopy: distention and irrigation of the knee, shoulder, and small joints, during diagnostic and operative procedures

During hysteroscopic, cystoscopic and arthroscopic procedures, the 37~5 can be used to monitor fluid deficit.

Technological Characteristics

The technological characteristics of the Thermedx 37~5 are substantially equivalent to the predicate devices.

- Infrared for fluid heating as does Fluido®. This differs from the methods used by the Ranger® and Level 1® devices, but provides the same function of heating the irrigation fluid to approximately body temperature.
- Peristaltic pump for fluid delivery. The Dolphin® II, Fluido®, Ranger® and Level 1® use pressure vessels to achieve the same pressure ranges, and the HydroFlex® uses a centrifugal pump, however neither the pressure vessels nor the centrifugal pump can measure flow as with a peristaltic pump can.
- Fluid Deficit Monitoring. Load-cells are used to measure fluid volumes and deficit as does the Dolphin® II.
- Pressure transducers to measure line pressure as does the Dolphin® II. The locations used do differ, the 37~5 transducers (dual) are located in the system instead of at the end of the tubing as is the Dolphin's single transducer. Both the 37~5 and HydroFlex® contain a pressure relief valve the Dolphin® II lacks providing additional over pressure protection.
- Both the 37~5 and HydroFlex® provide an additional safety feature, not available on the other predicate devices; this feature adds a database of pressures/flow rates/temperatures by procedure, which limit these settings to safe ranges.

Summary of Testing

Non-clinical performance testing has been performed to ensure the device is safe and effective and meets the associated clinical requirements. In order to verify performance, testing included the following:

1. Simulated Laparoscopy
2. Simulated Uterine Distensions
3. Over-temperature, Over-pressure, Over-Flow, and Over-Deficit testing.
4. Electrical Safety Testing in accordance to IEC 60601-1 electrical safety standards

These tests demonstrate the device meets all performance specifications

Conclusion

This 510(k) Notification demonstrates the substantial equivalence of the Thermedx 37~5 using the substantial equivalence criteria in FDA's K86-3 510(k) Guidance. The new device has the same intended use as the predicate devices, and the minor differences in indications for use statements do not alter the device's intended therapeutic effect. The new device also has similar technological characteristics to those of the predicate devices, and the minor differences are not significant with respect to the safety or effectiveness of the new device.

All statements and representations set forth above regarding or related to "substantially equivalent" or "substantial equivalence" are in the limited context of the definition and purpose of substantial equivalence in the Federal Food, Drug, and Cosmetic Act, as amended, and applicable regulations of the Food and Drug Administration, and are not made in the context of, for any purpose related to, or as an admission against interest under, any other laws or regulations, including patent laws (whether in the context of patent infringement or otherwise).



DEPARTMENT OF HEALTH & HUMAN SERVICES

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

JUL 29 2010

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

Re: K091939

Trade/Device Name: Thermedx 37~5™ Fluid Management System
Regulation Number: 21 CFR§ 884.1700
Regulation Name: Hysteroscopic insufflator
Regulatory Class: II
Product Code: HIG, LGZ, HRX
Dated: April 5, 2010
Received: April 7, 2010

Dear Mr. 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.

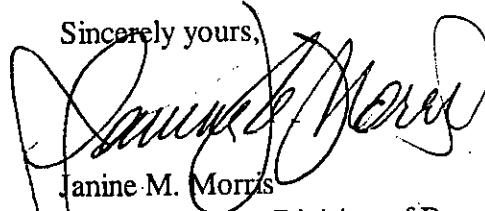
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR 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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 <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 Small Manufacturers, International and Consumer Assistance 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,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Form (Text Version)

Indications for Use

510(k) Number (if known): K091939

Device Name: Thermedx 37~5™ Fluid Management System

Indications for Use: The 37~5 is a multi-purpose fluid management system indicated for the following:

- Laparoscopy: warming fluids for irrigation and aspiration
- Hysteroscopy: uterine distention during diagnostic and operative procedures
- Cystoscopy: distention of the bladder during diagnostic and operative procedures (with optional fluid warming)
- Arthroscopy: distention and irrigation of the knee, shoulder, and small joints, during diagnostic and operative procedures

During hysteroscopic, cystoscopic and arthroscopic procedures, the 37~5 can be used to monitor fluid deficit.

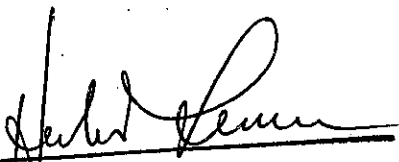
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K091939

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