November 4, 2021

Thermedx, LLC
Daniel Marijan
Quality and Regulatory Manager
31200 Solon Rd Unit 1
Solon, Ohio 44139

Re: K210628
Trade/Device Name: X-FLO Fluid Management System
Regulation Number: 21 CFR 884.1700
Regulation Name: Hysteroscopic Insufflator
Regulatory Class: II
Product Code: HIG, LGZ, HRX
Dated: October 4, 2021
Received: October 6, 2021

Dear Daniel Marijan:

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,

for
Jason R. Roberts, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210628

Device Name
X-FLO Fluid Management System

Indications for Use *(Describe)*
The X-FLO Fluid Management System is intended to:
• Warm and pump fluid, via intravenous (IV) bags or fluid bottles, to provide fluid distention and flushing of the uterus for gynecology procedures. The device can also measure fluid deficit of the surgical procedure.
• Warm and pump fluid, via IV bags or fluid bottles, to provide fluid distention and flushing of the bladder and kidneys, or general distention and flushing, for urological procedures. The device can also measure fluid deficit of the surgical procedure.
• Warm and pump fluid, via IV bags or fluid bottles, to provide fluid distention and flushing of the shoulder, knee, or other small joints for orthopedic procedures. The device can also measure fluid deficit of the surgical procedure.

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.

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510(k) Summary

I. SUBMITTER INFORMATION

Thermedx, LLC
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Phone: 440-542-0883
Fax: 440-542-0920

Contact Person: Daniel Marijan; Quality & Regulatory Manager
Email: dmarijan@thermedx.com
Phone: 440-542-0883

Date Prepared: November 3, 2021

II. DEVICE INFORMATION

Name of Device: X-FLO Fluid Management System
Common or Usual Name: Hysteroscopic Insufflator
Classification Name: Insufflator, Hysteroscopic
Regulatory Class: II
Regulation Number: 21 CFR 884.1700
Primary Product Code: HIG (Insufflator, Hysteroscopic)
Secondary Product Codes: LGZ (Warmer, Thermal, Infusion Fluid), HRX (Arthroscope)

III. PREDICATE DEVICE IDENTIFICATION

Name of Device: FluidSmart, K172048

The predicate device has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The X-FLO Fluid Management System ("X-FLO") (P/N 01910), with an optional deficit module (P/N 01601) is intended for fluid distention, fluid warming, and fluid volume/deficit measurements, as well as external suction regulation pertaining to deficit measurements for diagnostic and/or operative endoscopic procedures within gynecology, urology, and orthopedic disciplines.

The X-FLO utilizes a touchscreen user interface and performs fluid pressurization, warming, and volume/deficit monitoring functions. More specifically, the device employs a peristaltic pump to pressurize and deliver fluid to the surgical site for distending and continually flushing the surgical site for visualization purposes, utilizes infrared lamps to optionally warm the fluid to body temperature, and uses fluid bag weight to monitor fluid inflow.

Regarding the optional deficit monitoring function, the device utilizes external suction to return fluid from the surgical site. The X-FLO monitors and adjusts the vacuum level to the operator selected setpoint by opening the suction line to atmosphere if necessary. Once the fluid is returned from the surgical site, the single-use deficit cartridge measures the fluid volume collected, prior to transfer to fluid collection equipment and/or the hospital's waste disposal system.

The X-FLO is controlled via a Graphical User Interface (GUI), wherein the user is guided to select a surgical discipline and a procedure type. Once selected, the user can input the desired setpoint within the established minimum and maximum parameters for that procedure type. As set forth below, the X-FLO can operate in Pressure Control (the default control), Flow Control, or X-Control. Each control view has defaults and adjustment ranges for fluid pressure, flow, temperature, deficit alarm, and external suction regulation.

In addition to adjusting the fluid pressure setpoint via the GUI, the user may optionally utilize a foot pedal included with the X-FLO to temporarily increase the fluid pressure. By pressing the foot pedal, the user initiates an increase in fluid pressure. The amount of the increase is user configurable but can never exceed the maximum allowable fluid pressure for the procedure. When the user desires to have the fluid pressure return to the setpoint, the foot pedal is released.

There are several single use tubing sets available as accessories to the X-FLO system including the following:

- Inflow Set - CAT# XT8000 Part# 01790
  - Sterile. Includes inflow tubing and fluid cartridge assembly. This tubing set carries fluid from fluid vessels hung from hooks on the Main Unit, through the fluid cartridge assembly inserted into the Main Unit of the X-Flo system, and to the scope.
- Inflow Outflow Set – CAT# XT8100 Part# 01800
  - Sterile. Includes the Inflow Set (01790) and dual outflow tubing (01818, from scope and underbody drape and/or auxiliary floor suction device as applicable).
- Uro Inflow Outflow + CBI Set – CAT# XT8200 Part# 01805
  - Sterile. Includes the Urology Inflow Outflow Set (01990) with continuous bladder irrigation(CBI) tubing (01819).
- Urology Inflow Outflow Set – CAT# XT8300 Part# 01990
  - Sterile. Includes the Inflow Set (01790) and dual outflow tubing (01919, from scope and underbody drape and/or auxiliary floor suction device as applicable). The dual outflow tubing also allows for the addition of an optional tissue or kidney stone trap.
- Urology Morcellator Inflow Outflow Set – CAT# XT8400 Part# 02000
  - Sterile. Includes the Inflow Set (01790) and dual outflow tubing (01918, from scope and morcellator as applicable) with tissue trap.
- Deficit Set + CBI – CAT# XT8500 Part# 01820
  - Includes sterile and nonsterile components. Includes the Deficit Set (01810) and CBI tubing (01819). The only non-sterile component is the deficit cartridge.

- Deficit Set – CAT# XT8600 Part# 01810
  - Includes sterile and nonsterile components. Includes the Inflow Set (01790) and 2 outflow tubing sets: 1) dual outflow tubing (01918, from scope and hysteroscopic tissue removal system as applicable) with tissue trap; and 2) dual outflow tubing (01817, from underbody drape and auxiliary floor suction device as applicable) with deficit cartridge (01880). The only non-sterile component is the deficit cartridge.
- 17cc Tissue Trap Kit Part# 02071
  - Nonsterile 17 cc Tissue Trap assemblies that can be installed on applicable sets for procedures that require multiple tissue traps.
- 50 cc Tissue Trap Kit Part# 02072
  - Nonsterile 50 cc Tissue Trap assemblies that can be installed on applicable sets for procedures that require multiple tissue traps.

The tubing sets are made of sterile and non-sterile components, as indicated above, based on their use. The sterile components are indirect tissue contact, while the nonsterile components are non-tissue contact. The sets are made up of a polycarbonate cartridge connected to polyvinyl chloride (PVC) tubing with connectors made of multiple materials including nylon, PVC, polycarbonate, silicone, polytetrafluoroethylene (PTFE), and acrylonitrile butadiene styrene (ABS).

V. INDICATIONS FOR USE

The X-FLO Fluid Management System is intended to:

- Warm and pump fluid, via intravenous (IV) bags or fluid bottles, to provide fluid distention and flushing of the uterus for gynecology procedures. The device can also measure fluid deficit of the surgical procedure.
- Warm and pump fluid, via IV bags or fluid bottles, to provide fluid distention and flushing of the bladder and kidneys, or general distention and flushing, for urological procedures. The device can also measure fluid deficit of the surgical procedure.
- Warm and pump fluid, via IV bags or fluid bottles, to provide fluid distention and flushing of the shoulder, knee, or other small joints for orthopedic procedures. The device can also measure fluid deficit of the surgical procedure.

The Indications for Use of the subject device and predicate device are similar. The Indications for Use of the predicate device is as follows:

> 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.

The indications for use of the subject device include details of the procedures and expected functions of the subject device and the subject device is not indicated for use in laparoscopic procedures. The Indications for use of the predicate device indicate that the predicate device can be used for the laparoscopic procedures. There are no intended use concerns with the subject device indications for use statement.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

See the table below for a comparison of the technological characteristics of the X-FLO Fluid Management system to the predicate device.

		X-FLO Subject Device K210628	FluidSmart Predicate Device K172048	Summary
General Attributes	**Manufacturer Name**	Thermedx, LLC		The X-FLO has similar general attributes to the FluidSmart. The difference in device accessories is explained below in the Deficit Monitoring section. The difference in power does not raise different questions of safety and effectiveness.
	Device Description	A surgical fluid management system using a pump for delivering pressurized fluid. Monitors fluid deficit and warms fluid		
	Device Accessories	Various tubing sets; Includes optional deficit module for deficit monitoring	Various tubing sets; Includes canister ring for deficit monitoring	
	Location of Use	Operating Room or Physician Office		
	User Interface	Touch screen with a graphical interface displaying measured temperature, pressure, and deficit.		
	Software controlled	Yes		
	Power	120-240±10% VAC, 50/60 Hz	120V±5% VAC, 60Hz	
	Disposables Component Materials	EPDM, polycarbonate, PVC, nylon, adhesive, silicone, PTFE, cotton, polypropylene, ABS	Polycarbonate cartridge; PVC tubing; ABS and nylon fittings; and PTFE air vent	
	Tubing Sterile?	Yes, for all indirect tissue contacting tubing sets		
Irrigation Fluid Warming	**Irrigation Fluid / Warming**	Yes		The difference in Fluid Warming Rate for the X-FLO does not raise different questions of safety and effectiveness.
	Heating Technology	Infrared lamps		
	Fluid Warming Rate	Capable of increasing inlet fluid temperature from 18 °C ± 1 °C to 40 °C ± 3 °C for flow rates < 800 mL/min Capable of heating 18 ±1 °C inlet fluid to a 15 ±3 °C temperature rise at flow rates of >800 mL/min.	Capable of increasing inlet fluid temperature from 15.5 °C to 40 °C for flow rates < 500 ml/min	
	Maximum Set point	40 °C		
	Temperature Measurement	Irrigation fluid temperature measured at exit from the cartridge component of the tubing set		
	Temperature Displayed	Irrigation fluid temperature displayed at GUI.		
	Initial Temperature Signal	Set point +3 °C (43 °C max)		

Fluid Delivery	**Pressure / Pumping Mechanism**	Peristaltic pump with ability to reverse to relieve pressure		The X-FLO can hold four 5-Liter fluid vessels at a time. This volume increase does not raise different questions of safety and effectiveness. The maximum distention pressure has increased from 300 mmHg to 350 mmHg for ureteroscopy procedures only. The pressure increase does not raise different questions of safety and effectiveness.
	Pressure Measurement Mechanism	Dual transducers measuring fluid pressure		
	Maximum Flow Rate	1200 mL/min		
	Fluid Pressure	30-350 mmHg	30-300 mmHg	
	Procedure-based limits and ranges	Yes, default settings and limits established for pressure, flowrate, temperature, and suction pressure		
	Maximum Fluid Vessel Size (number of vessels in parentheses)	(4) 5-Liter	(2) 5-Liter	
	Max Fluid Capacity	5500 g per hook		
	Fluid Weight Accuracy	±5 mL	±10% or 250 mL	
	Temporary Pressure Increase Mechanism	Foot pedal or User interface	User interface	The foot pedal has been added as a feature to allow for a physician controlled, configurable, temporary pressure increase within the procedural limits established by X-FLO. The additional foot pedal does not raise different questions of safety and effectiveness.
Deficit Monitoring	**Fluid Deficit Monitoring**	Yes		The X-FLO, with the optional deficit module, calculates deficit based on fluid flow through a deficit cartridge and, therefore, does not require that the fluid returning from the surgical site to be collected in canisters and weighed, like the predicate device. The subject device also uses suction to pass fluid through the deficit cartridge. The change to deficit monitoring does not raise different questions or safety and effectiveness. Both methods can be evaluated through performance testing.
	Monitoring Accuracy Specification	1 – 1000 mL: ± 75 mL 1000 – 2500 mL: ± 5 % 2500 – 5000 mL: ± 3 % ≥ 5000 mL: ± 2.2 %	The greater of 250ml or 10% of the volume pumped	
	Measurement Means	Measurement by flow	Measurement by weight	
	Fluid Deficit Display	Displayed on GUI		
	External Suction Regulation	0-400 mmHg Suction Setpoint Range	None	
Safety Features	**Information Signals**	Visual and Audible		The X-FLO offers similar safety features to the predicate device, with the same types of information signals.
	Over-pressure	Audible and visual notifications and disable pumping if the fluid pressure exceeds the setpoint by the greater of 10% or 12 mmHg. Disable pumping prior to irrigation pressure exceeding the maximum set point by more than the higher of 20% of setpoint or 50 mmHg.	Audible and visual notification and fluid flow suspension if the fluid pressure is outside the setpoint by the greater of ±10% or 12 mmHg. An automatic reset shall occur when values return to the acceptable range.	

	Over-temperature	The device will disable the lamps if the fluid temperature reaches 41.5 ± 1 ℃. The device will disable pumping if the actual fluid temperature reaches 46 ± 1 ℃	The device flow will be disabled If the outlet fluid temperature exceeds set-point + 3 ℃.	
	Over-deficit (Isotonic Solutions)	The device will disable pumping when the default setpoint or maximum deficit volume (2,500 mL) is reached	If the fluid deficit exceeds the set point, the device shall produce audible and visible notifications and suspend fluid flow. Users may increase the deficit limit to resume fluid flow if the current limit is below the max allowable level.	
	Over-deficit (Hypotonic Solutions)	The device will disable pumping and provide audible notification when the deficit level reaches the deficit alarm setpoint inputted by the user. The device will disable pumping and provide audible notification when the maximum allowable deficit level of 2,500 mL is reached if the fluids used are a combination of isotonic and hypotonic. The device will disable pumping when the maximum deficit of 1,000 mL is reached.		
	Fluid Volume	Notify the user when a vessel is 300 ± 50 mL from empty. Notify the user when a vessel is empty; defined as ≤ 150 grams.	Indicate that the vessel is empty or low if the measured fluid level is less than 50 mL.	

VII. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING

The following performance data has been provided in support of the substantial equivalence determination. The subject device was evaluated according to the recommendations outlined in the 1995 FDA guidance document *"Hysteroscopic and Laparoscopic Insufflators."*

<u>Biocompatibility testing</u>

The biocompatibility evaluation for the X-FLO Fluid Management System single use tubing sets was conducted in accordance with 2020 FDA guidance document *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process."* The following tests were conducted:

- Cytotoxicity (ISO 10993-5:2009)
- Sensitization (ISO 10993-10:2010)
- Irritation (ISO 10993-10:2010)
- Acute Systemic Toxicity (ISO 10993-11:2017)

The X-FLO Fluid Management System single use tubing sets have been assessed, based on the tissue contact and contact duration, an externally communicating medical device with tissue/bone/dentin contact for a limited (<24 hours) exposure duration.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the X-FLO Fluid Management System. The system complies with IEC 60601-1:2005 + CORR. 1 (2006) + CORR. 2 (2007) + AM1 (2012), IEC 60601-1-2:2014, and IEC 60601-6:2010 + A1:2013.

Software Verification and Validation Testing

Software verification and validation testing was conducted, and documentation was provided as recommended by the 2005 FDA guidance document, *"Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."* The software for this device was considered as a "major" level of concern since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator.

Sterility and Shelf-Life Testing

The applicable accessories were sterilized via Ethylene Oxide Sterilization per ISO 11135:2014.

The sterile tubing accessories have a shelf life of 6 months. Shelf-life testing was performed using accelerated aging per ASTM F198-16 with visual inspection, dye penetration testing per ASTM F1929-15 and seal strength testing per ASTM F88 completed on aged devices.

Bench testing

- Evaluated if the specifications are met as expected in the simulated use, including system functionality testing of the following:
    - Alarm sound levels
    - Tubing and cartridge leak testing
    - Tubing mechanical strength
    - Fluid sensing
    - Fluid compatibility with sterile water, lactated ringers solution, 5 % mannitol solution, 1.5 % glycine solution, 0.9% saline solution, and sorbitol solution.
    - Irrigation pressure controls with three different hysteroscope models, per the hysteroscopic and laparoscopic insufflator guidance
- Over-temperature, over-pressure, and over-deficit testing.
- Tissue trap capacity, deficit calculation accuracy, empty fluid bag detection, temperature accuracy, and pressure and flowrate-accuracy testing.

VIII. CONCLUSIONS

The performance data summarized above demonstrate that the subject device (X-FLO Fluid Management System) is as safe and effective as the predicate device (FluidSmart). The subject device is substantially equivalent to the predicate device.