March 17, 2023

FemDx Medsystems, Inc.
℅ Sevrina Ciucci
Regulatory Consultant
Regulatory Consulting Services LLC
2336 Walsh Avenue, Suite A
Santa Clara, CA 95051

Re: K221965
Trade/Device Name: FemDx FalloView™
Regulation Number: 21 CFR§ 884.1690
Regulation Name: Hysteroscope and Accessories
Regulatory Class: II
Product Code: MKO, HIH
Dated: February 16, 2023
Received: February 17, 2023

Dear Sevrina Ciucci:

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 and Part 809); 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,

Jason Roberts -S

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)*
K221965

Device Name
FemDx FalloView™

Indications for Use *(Describe)*
The FemDx FalloView™ is intended for visualization of the cervical canal, uterine cavity, and proximal fallopian tube(s) during diagnostic gynecological procedures.

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

Date Prepared:	March 15, 2023
Submitter:	FemDx Medsystems, Inc. 2336 Walsh Avenue, Suite A Santa Clara, CA 95051
Contact Person:	Xi Francis, CEO Email: Ashlee@femdxmedical.com
Trade/Device Name:	FemDx FalloView™
Common Name:	Falloposcope, Hysteroscope
Classification Regulation:	21 CFR §884.1690, Hysteroscope and accessories
Product Codes:	MKO, HIH
Device Classification:	Class II
Classification Panel:	Obstetrics/Gynecology
Primary Predicate:	Conceptus Fallopian Tube Catheterization with Microendoscopy (FTCM) System (K962587)
Reference Devices:	LiNA Medical ApS LiNA Opera Scope (K171113) Cook Incorporated Rösch-Thurmond Fallopian Tube Catheterization Set and Fallopian Tube Catheterization Set (K171604) Aveta System, Aveta Disposable Hysteroscope (Pearl/Opal/Coral), Aveta Disposable Cystoscope (Coral) (K213171)

Device Description

The FemDx FalloView™ is a disposable, hand-held, battery-operated endoscope that contains a 4.7 mm hysteroscopic cannula, a 1.2 mm falloposcopic catheter, and a visualization system. The catheter is integrated inside the cannula center lumen and can be deployed, retracted, or rotated. The cannula includes a lumen and a proximal female luer lock port for saline irrigation. The visualization system includes a camera module positioned at the tip of the catheter, a controller board, an LCD display integrated into the device's handle, and LED/fiber optic illumination. The FemDx FalloView™ contains embedded software designed to display the real time image on the LCD display, control the illumination light level, and capture a screenshot. The captured image can be transmitted to a computer via Bluetooth and then accessed using the FalloView™ Image Viewer, a separate PC based software application.

Indications for Use

The FemDx FalloView™ is intended for visualization of the cervical canal, uterine cavity, and proximal fallopian tube(s) during diagnostic gynecological procedures.

Substantial Equivalence Discussion

The FemDx FalloView™ is substantially equivalent to Conceptus Fallopian Tube Catheterization with Microendoscopy (FTCM) System (K962587). Table 1 compares the FemDx FalloView™ to the predicate device. The different technological characteristics exist in other previously cleared FDA devices of the same type and do not raise different questions of safety and effectiveness than the predicate device.

Table 1: Substantial Equivalence Table

Characteristic	Predicate Device Conceptus FTCM System K962587	Subject Device FemDx FalloView™ K221965
Device Classification	II	II
Classification Name	Falloposcope	Falloposcope, Hysteroscope and Accessories
Regulation Number	884.1690	884.1690
Product Code	MKO	MKO, HIH
Indications for Use	The Conceptus FTCM System is intended for use in selective catheterization / cannulation of the fallopian tubes in order to evaluate proximal tubal occlusion or patency under direct visualization.	The FemDx FalloView is intended for visualization of the cervical canal, uterine cavity, and proximal fallopian tube(s) during diagnostic gynecological procedures.
Components	Soft Seal Cervical Catheter, Soft Torque Uterine Catheter (including Mandrel and Accessory Valve), and/or Articulating Tip Hysteroscope, Variable Softness Catheter, Guidewires (Robust Guidewire, Traveler Guidewire, Supple Guidewire, and Pirouette Guidewire), and a Microendoscope with Eyepiece	•Handle with LCD display unit, battery pull tab, and control button to turn device on and off. •Cannula with stainless -steel hypo-tube that forms the inner lumen of the cannula that houses the catheter. The distal tip incorporates a low intensity LED to illuminate the uterus. •Catheter with a CMOS-chip endoscope that maintains an image of the tissue in contact with its surface. Contains an LED and camera connected to the controller board.
Intended User	Trained Medical Professionals	Trained Medical Professionals
Site of Use	Hospitals and Physicians Offices	Hospitals and Physicians Offices
Anatomical Use	Proximal Fallopian Tube(s)	Cervical Canal, Uterine Cavity, and Proximal Fallopian Tube(s)
Cannula Working Length	Unknown	250 mm
Cannula Outer Diameter	Unknown	4.7 mm

Characteristic	Predicate Device	Subject Device
	Conceptus FTCM System	**FemDx FalloView™**
	K962587	**K221965**
Cannula Tip Design	Soft Torque Uterine Catheter: curved tip	Rounded polymer tip with angled distal portion (10 mm approx. 15°)
Cannula Lumens	Soft Seal Cervical Catheter: dual lumen Soft Torque Uterine Catheter and Variable Softness Catheter: single lumen	Three lumens
Inflow / Outflow Design	Inflow: Inflow occurs through a port on the Variable Softness catheter Outflow: No outflow	Inflow: Inflow occurs through a port on the proximal side of the cannula. Outflow: No outflow
Inflow Pressure Limit	Unknown, use a syringe, or irrigation tube	75 mmHg
Catheter Working Length	Unknown	108 mm (extension beyond cannula tip)
Catheter Outer Tip Diameter	Variable Softness Catheter: 1.2 to 1.3 mm according to Surrey et.al.1996**Error! Bookmark not defined.**	1.2 mm
Catheter Tip Design	Unknown	Rounded polymer
Imaging Technology	Microendoscope: fiberscope with optical fiber bundle for pixels	CMOS Camera Module
LCD Display Size	Not applicable, use eyepiece or external video system for display	3.5 inches (diagonal)
Image Resolution	Unknown	40,000 pixels Pixel size 1.75 um
Illumination Light Source	External light source. Fiber optics in hysteroscope and microendoscope extend the light energy.	LED at tip of the cannula and internal LED with fiber optics that extends to the tip of the catheter.
Light at 20 mm from target. Range high to low level [LUX]	Not applicable	378 - 192 LUX
Image Transmission	Not applicable	Transits images from CMOS camera module to integrated LCD display.
Energy Source	Not applicable	Handpiece: 9V battery, regulated to 3.3V internally
Sterilization	Unknown	Ethylene Oxide (EO)
Image Saving Software	Not applicable	Yes

Non-Clinical Testing

To demonstrate safety and effectiveness of the FemDx FalloView™ and show substantial equivalence to the predicate device, a comprehensive series of non-clinical tests were completed including mechanical dimensional and performance, electrical hardware/software performance, optical performance, and safety testing in accordance with FDA's guidance, "Hysteroscopes and Gynecological Laparoscopes Submission

Guidance for a 510(k)". The FemDx FalloView™ passed all applicable testing in accordance with internal requirements and national and international standards. The results demonstrate that the FemDx FalloView™ satisfies the performance, functional, and safety requirements relative to the product specifications, risk analyses, and Instructions for Use, and does not raise different questions of safety and effectiveness than the predicate device.

The non-clinical tests relied on for a determination of substantial equivalence are listed below.

- "Power on" testing including battery lifetime.
- Image quality comparative testing
  - Field of view, Direction of view ISO 8600-3
  - Image color quality
  - Image resolution ISO 8600-5
  - Depth of field
  - Image signal to noise ratio
  - Dynamic range
  - Image geometric distortion
  - Image intensity uniformity
- Flow rate and leakage testing ISO 10555-1
- Dimensional testing
  - Maximum width of insertion portion per ISO 8600-4
  - Cannula maximum insertion width ISO 8600-4
  - Catheter shaft maximal outer diameter ISO 8600-4
- Mechanical testing for bending (displacement), tensile strength, and torque
  - Catheter insertion force, deployment force, and retraction force
  - Cannula and catheter bending force
  - Cannula and catheter rotational force
- Mechanical strength
  - Catheter sheath tensile strength
  - Catheter stiffness/bending curvature radius
  - Catheter torsional strength
  - Cannula tensile strength
  - Cannula torsional strength
- Visualization and illumination design validation testing including equipment compatibility.
  - Cannula and catheter insertion testing within a uterus and fallopian tube model
  - Illumination testing within a uterus and fallopian tube model
- LED illumination light level testing
- Thermal safety testing
- Photobiological safety IEC 62471
- Packaging testing ISO 11607-1
  - Simulated shipping conditions ASTM D4169
  - Climatic conditioning ASTM D4332

  - Package and seal integrity visual inspection ASTM F1886/F1186M
  - Bubble leak ASTM F2096
  - Aseptic opening ISO 11607-1
  - Seal strength ASTM F88/F88M
  - Seal width ASTM F2203
- Biocompatibility ISO 10993-1
  - Cytotoxicity ISO 10993-5
  - Sensitization ISO 10993-10
  - Irritation ISO 10993-10
- Sterilization ISO 11135
- EO and ECH residual testing ISO 10993-7
- Software verification and validation IEC 62304
- Electrical safety IEC 60601-1
- Electromagnetic compatibility IEC 60601-1-2 (EMC and Immunity)

Conclusion

The FemDx FalloView™ is substantially equivalent to the predicate device.