August 16, 2018

UVision360 Inc.
% Dave Yungvirt
Official Correspondent
Third Party Review Group, LLC
The Old Station House
24 Lackawanna Place
Millburn, New Jersey 07041

Re: K181909
Trade/Device Name: Luminelle DTx Hysteroscopy System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FAJ, HIH
Dated: July 14, 2018
Received: July 17, 2018

Dear Dave Yungvirt:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Glenn B. Bell -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181909

Device Name
Luminelle DTx Hysteroscopy System

Indications for Use *(Describe)*
Hysteroscopy: The Luminelle DTx Hysteroscopy System is used to permit direct viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic and surgical procedures.
Note: Hysteroscopes are used as tools to access the uterine cavity and are not, in and of themselves, a method of surgery.

Generally recognized indications for diagnostic hysteroscopy include:
• Abnormal bleeding
• Infertility and pregnancy wastage
• Evaluation of abnormal hysterosalpingogram
• Intrauterine foreign body
• Amenorrhea
• Pelvic pain

Generally recognized indications for operative hysteroscopy include:
• Directed endometrial biopsy
• Polypectomy
• Submucous myomectomy
• Transection of intrauterine adhesions
• Transection of intrauterine septa
• Endometrial ablation

Cystoscopy: The Luminelle DTx Hysteroscopy System is intended for use in endoscopic access to and examination of the lower urinary tract, including the bladder. When combined with accessory instruments, the System allows the user to perform various diagnostic and therapeutic 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 Summary Prepared:	August 15, 2018	
510(k) Owner:	UVision360 Inc.	
Contact Person:	Allison London Brown CEO, UVision360 Inc. 4441-106 Six Forks Road, #179 Raleigh, NC 27609	
Device Name:	Trade Name:	Luminelle DTx Hysteroscopy System
	Common Name:	Hysteroscope (and accessories); Cystoscope (and accessories)
	Regulation:	876:1500 Endoscope and accessories
	Class:	II
	Product Code:	FAJ, HIH
Predicate Device(s):	Primary Predicate	K072180 Cogentix Flexible Video Cystoscope with Digital Video Processor and Disposable EndoSheath Systems
	Secondary Predicate	K071127 Vision-Sciences Flexible Cystoscope with EndoSheath System (with additional Hysteroscope Indications for use)
		The predicate devices have not been subject to a design related recall.

Device Description: The Luminelle DTx Hysteroscopy System is comprised of four components:

1) Luminelle DTx Hysteroscope - a non-sterile, reusable flexible hysteroscope with an integrated light source, light fiber bundle and CMOS sensor.

2) The Luminelle DTx 360º Rotatable Disposable Sheath - a sterile, two-part sheath installed over the insertion tube of the Hysteroscope and comprised of the Operative Introducer and the 360º RotoSheath. The Operative Introducer contains an operative channel for inserting surgical accessories, two fluid management lines (inflow/outflow), and a channel to protect the scope insertion tube. The 360º RotoSheath allows for rotational positioning of the camera and provides rigidity to the Scope/Introducer assembly.

3) Luminelle Communication Cable - a cable that provides both the power to the hysteroscope and transmits the image.

4) Luminelle Control Hub - the main power supply, image converter and visualization connection. The Control Hub has both HDMI and

USB connectors for connection to a monitor and/or a PC. USB and HDMI cables are provided in the package.

The Luminelle DTx Hysteroscope, Communication Cable, Control Hub, USB and HDMI cables and power cord are provided together in a single package. The 360º Rotatable Disposable Sheath is provided in a separate sterile package. The 360º Rotatable Disposable Sheath is required for use with the Hysteroscope, therefore it is a component of the system and not an accessory to the system.

The CMOS sensor and fiber optic illumination bundles are contained in the Hysteroscope Insertion Tube. The insertion tube length is 29.8 cm (11.73 in.) and the outside diameter is 1.95 mm (0.077 in.). The Luminelle DTx Hysteroscope is packaged in a white form fit tray with a clear slide-on cover. The tray is made of high-impact polystyrene (HIPS). The clear cover is made of polyethylene terephthalate with glycol (PETG).

The Luminelle 360º RotoSheath has a working length of 24.0 cm (9.45 in.) with an outside diameter of 5.7 mm (0.244 in.). The Luminelle Operative Introducer has an outside diameter of 4.8 mm (0.189 in.) and the inside diameter of the operative channel is 1.85 mm (0.073 in.).

Both the Luminelle 360º RotoSheath and Luminelle Operative Introducer are supplied as a single assembled unit packaged in a bottom tray with retaining lid made of polyethylene terephthalate with glycol (PETG) and sealed with Tyvek. The assembled package is sterilized using ethylene oxide (EO).

The Control Hub supplies power to the Hysteroscope via a reusable Communication Cable. The CMOS sensors have a processor that converts the visual image into data to be transferred. A processor in the Control Hub converts this image data into streaming HDMI language, takes still images when the button is pushed, and also controls the light exposure during changing light conditions.

Visualization on a video monitor is provided via a HDMI cable, and image transfer to a PC is provided via a Type A USB cable. A 12V DC, 3A power adapter is also provided. Technical specifications for these reusable components are provided in the Instructions for Use.

Indications for Use Statement:

Hysteroscopy: The Luminelle DTx Hysteroscopy System is used to permit direct viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic and surgical procedures.

Note: Hysteroscopes are used as tools to access the uterine cavity and are not, in and of themselves, a method of surgery.

Generally recognized indications for diagnostic hysteroscopy include:

- Abnormal bleeding
- Infertility and pregnancy wastage
- Evaluation of abnormal hysterosalpingogram
- Intrauterine foreign body
- Amenorrhea
- Pelvic pain

Generally recognized indications for operative hysteroscopy include:

- Directed endometrial biopsy
- Polypectomy
- Submucous myomectomy
- Transection of intrauterine adhesions
- Transection of intrauterine septa
- Endometrial ablation

Cystoscopy: The Luminelle DTx Hysteroscopy System is intended for use in endoscopic access to and examination of the lower urinary tract, including the bladder. When combined with accessory instruments, the System allows the user to perform various diagnostic and therapeutic procedures.

Device Comparisons			
Feature	**Proposed Luminelle DTx Hysteroscopy System**	**Primary Predicate Cogentix (K072180)**	**Secondary Predicate Vision-Sciences (K071127)**
Product Codes	HIH FAJ	FAJ (primary)	HIH (Primary) FAJ
	Conclusion: Both predicate devices combined have the same product codes as the subject device.		
Indications for Use (hysteroscopy)	Used to permit direct viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic and surgical procedures.	n/a	Used to permit direct viewing of the cervical canal and the uterine cavity for the purpose of performing diagnostic and therapeutic/surgical procedures.
	Conclusion: The proposed device and the secondary predicate device have the same indications for use for hysteroscopy.		

Device Comparisons			
Feature	**Proposed Luminelle DTx Hysteroscopy System**	**Primary Predicate Cogentix (K072180)**	**Secondary Predicate Vision-Sciences (K071127)**
Indications for Use (Cystoscopy)	The Luminelle DTx Hysteroscopy System is intended for use in endoscopic access to and examination of the lower urinary tract including the bladder. When combined with accessory instruments, the System allows the user to perform various diagnostic and therapeutic procedures.	The Cogentix Medical CST-5000/ 5000i Flexible Video Cystoscope/ Hysteroscope with Slide-On® EndoSheath® Technology is intended to be used for endoscopic access to and examination of the lower urinary tract, including the bladder. When combined with accessory instruments, the endoscopic system allows the user to perform various diagnostic and therapeutic procedures.	The CST-2000A and Slide-On EndoSheath System provides for endoscopic access and examination of the lower urinary tract, including the bladder, and using additional accessories, to perform various diagnostic and therapeutic procedures.
	Conclusion: All three devices have the same indications for use regarding cystoscopy.		
System Overview	Handheld AC powered hysteroscope/cystoscope, consisting of a reusable handle and insertion tube, and a sterile disposable sheath	Handheld AC powered hysteroscope/ cystoscope, consisting of reusable handle and insertion tube, and a sterile disposable sheath.	N/A: All technical information for the SE comparison will be taken from the primary predicate.
	Conclusion: Both the proposed and primary predicate are comprised of the same general system.		
Cannula Diameter	5.7 mm outer diameter	5.6 mm outer diameter	N/A: All technical information for the SE comparison will be taken from the primary predicate.
	Conclusion: Slight differences in the outer diameter do not raise different questions of safety and effectiveness.		
Scope Working Length	240 mm	370 mm	N/A: All technical information for the SE comparison will be taken from the primary predicate.
	Conclusion: Both the proposed and primary predicate have scope lengths typical for devices of this type and the differences do not raise different questions of safety and effectiveness.		

Device Comparisons			
Feature	**Proposed Luminelle DTx Hysteroscopy System**	**Primary Predicate Cogentix (K072180)**	**Secondary Predicate Vision-Sciences (K071127)**
Image Processing and Display	Image Processing: Digital Video Processor Display: Standard HD Monitor/TV.	Image Processing: Digital Video Processor Display: LCD Display	N/A: All technical information for the SE comparison will be taken from the primary predicate.
	Conclusion: The differences in types of do not raise different questions of safety and effectiveness.		
Image Transmission	Image transmitted from a video camera to the Digital Video Processor then to the display.	Image transmitted from a video camera to the Digital Video Processor then to the display.	N/A: All technical information for the SE comparison will be taken from the primary predicate.
	Conclusion: Both the proposed and primary predicate transmit the image the same way.		
Image Capture	Still image capture during a procedure by depressing a camera button on the handle.	Image and Video capture and retrieval capabilities on Digital Video Processor	N/A: All technical information for the SE comparison will be taken from the primary predicate.
	Conclusion: Predicate device requires purchase of a separate Digital Video Processor that has more recording capabilities than the proposed device. These differences do not raise different questions of safety and effectiveness for the intended uses.		
Instrument Channel Diameter	5 Fr. (1.7 mm)	6.3 Fr (2.1 mm)	N/A: All technical information for the SE comparison will be taken from the primary predicate
	Conclusion: While the subject device accommodates slightly smaller instruments than the predicate, this does not raise different questions of safety and effectiveness, as operative instruments are readily available in both sizes.		
Illumination Light Source	Integrated solid state LED light source with fiber optic transmission.	Integrated solid state LED light source with fiber optic transmission.	N/A: All technical information for the SE comparison will be taken from the primary predicate
	Conclusion: Both the proposed and primary predicate have the same illumination light source.		

Device Comparisons			
Feature	**Proposed Luminelle DTx Hysteroscopy System**	**Primary Predicate Cogentix (K072180)**	**Secondary Predicate Vision-Sciences (K071127)**
Objective Lens - Focal Length - Field of Vie - Direction of View	Focal Length: 5 – 50 mm Field of View: 120º in air Direction of View: Forward (0º)	Focal length: 3 – 50 mm Field of view: 110º in air Direction of View: Forward (0º)	N/A: All technical information for the SE comparison will be taken from the primary predicate
	Conclusion: Both the proposed and primary predicate have similar objective lens characteristics. The differences do not raise different questions on safety or effectiveness of the device.		
Image Resolution	CMOS chip is 400 x 400 pixels. USAF 1951 bar code Group-Element: 1-5	CCD chip specifications not stated in product literature.	N/A: All technical information for the SE comparison will be taken from the primary predicate
	Conclusion: Different chip technologies are used, but differences do not raise different questions on safety or effectiveness.		
Mode of Operation	Continuous	Continuous	N/A: All technical information for the SE comparison will be taken from the primary predicate
	Conclusion: Both the proposed and primary predicate are used in a continuous mode of operation.		
Electrical Safety	Compliant with requirements of IEC 60601-1; IEC 60601-2-18	Compliant with requirements of IEC 60601-1; IEC 60601-2-18	N/A: All technical information for the SE comparison will be taken from the primary predicate
	Conclusion: Both the proposed and primary predicate are compliant with the requirements of IEC 60601-1 and IEC 60601-2-18 for electrical safety.		
Thermal Safety	Compliant with requirements of IEC 60601-1; IEC 60601-2-18	Compliant with requirements of IEC 60601-1; IEC 60601-2-18	N/A: All technical information for the SE comparison will be taken from the primary predicate
	Conclusion: Both the proposed and primary predicate are compliant with the requirements of IEC 60601-1 and IEC 60601-2-18 for thermal safety.		

Device Comparisons			
Feature	**Proposed Luminelle DTx Hysteroscopy System**	**Primary Predicate Cogentix (K072180)**	**Secondary Predicate Vision-Sciences (K071127)**
Degree of Protection Against Electrical Shock	Type BF	Type BF	N/A: All technical information for the SE comparison will be taken from the primary predicate
	Conclusion: Both the proposed and primary predicate have the same degree of protection against electrical shock.		
Degree of Protection Against Invasion of Liquids	IPX7	Fully immersible (per reprocessing instructions)	N/A: All technical information for the SE comparison will be taken from the primary predicate
	Conclusion: Both the proposed and primary predicate can be immersed in liquids for reprocessing (the primary predicate does not have an IP rating).		
Patient Contacting Materials	Biocompatibility testing per ISO 10993	Biocompatibility testing per ISO 10993	N/A: All technical information for the SE comparison will be taken from the primary predicate.
	Conclusion: All three devices have patient contacting materials which have been tested per ISO 10993 for biocompatibility.		
Scope Reprocessing	Reprocessed between each use. When used as a hysteroscope, the scope is sterilized between uses. When used as a cystoscope, the scope is disinfected with a high-level disinfectant solution.	Reprocessed between each use. When used as a hysteroscope, the scope is sterilized between uses. When used as a cystoscope, the scope is disinfected with a high-level disinfectant solution.	N/A: All technical information for the SE comparison will be taken from the primary predicate.
	Conclusion: Both the proposed device and primary predicate are reprocessed the same way between each use, depending on whether it was used as a hysteroscope or cystoscope.		

Device Comparisons			
Feature	**Proposed Luminelle DTx Hysteroscopy System**	**Primary Predicate Cogentix (K072180)**	**Secondary Predicate Vision-Sciences (K071127)**
Disposable Sheath	Rotatable with a curved tip	Non-rotatable with an articulating tip	N/A: All technical information for the SE comparison will be taken from the primary predicate.
	Conclusion: Both the proposed device and primary predicate have sheaths which allow for adequate direction of the camera field of view to perform the intended use. The rotation capabilities of the proposed device allow the user to maintain a comfortable, upright grip on the scope handle while allowing for independent rotational positioning of the camera field of view. The difference does not raise any different questions on safety and effectiveness.		
Disposable Sheath	Disposable sheath with 4 channels; one for the camera, two for fluid delivery (inflow and outflow), and one for operative instruments.	Disposable sheath with 2 channels; one for the camera and one for fluid delivery or an operative instrument	N/A: All technical information for the SE comparison will be taken from the primary predicate.
	Conclusion: The protective sheath of the proposed device allows the user to administer fluids at the same time the operative channel is in use, providing more flexibility and control to the user. This difference does not raise different questions on safety and effectiveness.		

Performance Data: Performance testing was performed to verify that the performance of the Luminelle DTx Hysteroscopy System is substantially equivalent to currently marketed Cogentix scope (K072180). Testing included:

- optical resolution per ISO 8600
- biocompatibility per ISO 10993 including cytotoxicity, sensitization, and irritation
- electrical and thermal safety per IEC 60601-1
- electromagnetic compatibility per IEC 60601-1-2
- endoscope specific safety and performance per IEC 60601-2-18
- usability
- reprocessing validation per FDA reprocessing guidance
- sterilization validation per ISO 11135
- shelf life and packaging validation
- software validation per FDA software guidance for moderate level of concern

Overall Conclusions: The Luminelle DTx Hysteroscopy System has been shown to be substantially equivalent to the predicates