June 30, 2021

UVision360, Inc.
% Rita King
CEO and Senior Consultant
MethodSense, Inc.
1 Copley Pkwy, Ste. 410
Morrisville, NC 27560

Re: K210512
Trade/Device Name: LUMINELLE DTx System
Regulation Number: 21 CFR§ 884.1690
Regulation Name: Hysteroscope and accessories
Regulatory Class: II
Product Code: HIH, FAJ, HFF, FCK
Dated: June 1, 2021
Received: June 2, 2021

Dear Rita King:

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,

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)*
K210512

Device Name
LUMINELLE DTx System

Indications for Use *(Describe)*
Hysteroscopy:
The LUMINELLE DTx System is used to permit 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. When LUMINELLE DTx System is specifically used with the LUMINELLE Dx 360° Rotatable Disposable Sheath (Diagnostic), the system is limited to performing diagnostic procedures only. When the LUMINELLE DTx System is used with the LUMINELLE Bx 360° Rotatable Disposable Sheath (Biopsy), the system is limited to performing diagnostic procedures only. The Bx Sheath can be used for endometrial or lower urinary tract (including bladder) biopsy by aspiration with a syringe during diagnostic procedures.

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

Cystoscopy:

The LUMINELLE DTx 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.

NOTE: When LUMINELLE DTx System is specifically used with the LUMINELLE Dx 360° Rotatable Disposable Sheath (Diagnostic), the system is limited to performing diagnostic procedures only.
NOTE: When the LUMINELLE DTx System is used with the LUMINELLE Bx 360° Rotatable Disposable Sheath (Biopsy), the system is limited to performing diagnostic procedures only. The Bx Sheath can be used for endometrial or lower urinary tract (including bladder) biopsy by aspiration with a syringe during diagnostic 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Submitter: UVision360 Inc.
158 Wind Chime Ct.
Suite 201
Raleigh, NC 27615
Phone: 888-855-9360

Primary Contact: Rita King, CEO
MethodSense, Inc.
Email: ritaking@methodsense.com
Phone: 919-313-3961
Fax: 919-313-3979

Company Contact: Allison London Brown
CEO

Date Prepared: June 1, 2021

Device Name and Classification

Trade Name:	LUMINELLE DTx System
Common Name:	Hysteroscope and accessories, Endoscope and accessories
Classification:	Class II
Regulation Number:	21 CFR 884.1690 Hysteroscope and accessories 21 CFR 876.1500 Endoscope and accessories 21 CFR 884.1060 Endometrial Aspirator 21 CFR 876.1075 Gastroenterology-urology biopsy instrument
Classification Panel:	Obstetrics/Gynecology Gastroenterology/Urology
Product Code:	HIH Hysteroscope (And Accessories) FAJ Cystoscope And Accessories; Flexible/Rigid HFF Aspirator, Endometrial FCK Instrument, Biopsy, Suction

Predicate Device:

	Predicate Device
Trade Name	LUMINELLE DTx System
Common Name	Hysteroscope (and accessories); Cystoscope (and accessories)
510(k) Submitter / Holder	UVision360 Inc.
510(k) Number	K192278
Regulation Number	21 CFR 884.1690 Hysteroscope and accessories 21 CFR 876.1500 Endoscope and accessories
Classification Panel	Gastroenterology/Urology Obstetrics/Gynecology
Product Code	HIH Hysteroscope (And Accessories) FAJ Cystoscope And Accessories; Flexible/Rigid

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

Device Description

The LUMINELLE DTx System, previously known as the LUMINELLE DTx Hysteroscope System, originally received 510(k) clearance in 2018 as a hysteroscopic and cystoscopic system (K181909). In addition, LUMINELLE DTx Hysteroscopy System received 510(k) clearance in 2019 for the addition of a sheath component, LUMINELLE DTx 360º Rotatable Disposable Sheath Rigid to the system (K190827) and LUMINELLE Dx 360° Rotatable Disposable Sheath (Diagnostic) (K19227).

The LUMINELLE DTx System permits viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic and surgical procedures. The LUMINELLE DTx System is intended for use in endoscopic access to the examination of the lower urinary tract, including the bladder. When combined with accessory instruments, the LUMINELLE DTx System allows the user to perform various diagnostic and therapeutic procedures.

The LUMINELLE DTx System is comprised of the following components:

- LUMINELLE DTx Scope;
- LUMINELLE Communication Cable;
- LUMINELLE Control Hub;
- USB cable;
- HDMI cable, and;
- power cord.

UVision360, Inc. (hereafter UVision360) designed a new accessory, the LUMINELLE Bx 360° Rotatable Disposable Sheath (Biopsy) that is compatible with the LUMINELLE DTx System that permits direct viewing of the cervical canal and uterine cavity during biopsy procedures. LUMINELLE Bx 360° Rotatable Disposable Sheath (Biopsy) is a single use accessory and is made of the same materials as the previously cleared sheaths (K190827, K192278).

The LUMINELLE DTx Scope is reprocessed after each use, depending on the procedure. High Level Disinfection (HLD) solutions can be used to reprocess the LUMINELLE DTx Scope when used with a cystoscopy procedure. 0.6% Ortho-Phthalaldehyde (OPA), a chemical disinfectant, has been previously cleared for HLD. However, UVision360 has verified and validated an additional chemical, Steris Revital-Ox™ RESERT® High Level Disinfectant, for HLD with the LUMINELLE DTx System. Steris Revital-

Ox™ RESERT® High Level Disinfectant has been tested in order to determine that it identically cleans the LUMINELLE DTx Scope as 0.6% OPA and does not adversely affect the functionality of the LUMINELLE DTx System.

Before a hysteroscope procedure, the LUMINELLE DTx Scope must be sterilized to be reprocessed. In the previous submissions, Ethylene Oxide, qualified by Andersen Scientific, Inc., has been used to sterilize the LUMINELLE DTx Scope. An additional sterilization method, V-PRO® Low Temperature Sterilization, qualified by Steris located in Mentor, OH, has been validated and verified as an additional sterilization method to ensure that it properly sterilizes the LUMINELLE DTx Scope.

Indications for Use

Hysteroscopy:
The LUMINELLE DTx System is used to permit 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. When LUMINELLE DTx System is specifically used with the LUMINELLE Dx 360º Rotatable Disposable Sheath (Diagnostic), the system is limited to performing diagnostic procedures only. When the LUMINELLE DTx System is used with the LUMINELLE Bx 360° Rotatable Disposable Sheath (Biopsy), the system is limited to performing diagnostic procedures only. The Bx Sheath can be used for endometrial or lower urinary tract (including bladder) biopsy by aspiration with a syringe during diagnostic procedures.

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 use for operative hysteroscopy include:

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

Cystoscopy:

The LUMINELLE DTx 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.

NOTE: When LUMINELLE DTx System is specifically used with the LUMINELLE Dx 360º Rotatable Disposable Sheath (Diagnostic), the system is limited to performing diagnostic procedures only.

NOTE: When the LUMINELLE DTx System is used with the LUMINELLE Bx 360° Rotatable Disposable Sheath (Biopsy), the system is limited to performing diagnostic procedures only. The Bx Sheath can be used for endometrial or lower urinary tract (including bladder) biopsy by aspiration with a syringe during diagnostic procedures.

Substantial Equivalence

The table below provides a detailed comparison of the LUMINELLE DTx System to the predicate device.

Detailed Comparison of the Subject and Predicate Devices

Item	Subject Device LUMINELLE DTx System	Predicate Device LUMINELLE DTx Hysteroscopy System (K192278)	Comparison
Indications for Use	Hysteroscopy: The LUMINELLE DTx System is used to permit 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. When LUMINELLE DTx System is specifically used with the LUMINELLE Dx 360º Rotatable Disposable Sheath (Diagnostic), the system is limited to performing diagnostic procedures only. When the LUMINELLE DTx System is used with the LUMINELLE Bx 360° Rotatable Disposable Sheath (Biopsy), the system is limited to performing diagnostic procedures only. The Bx Sheath can be used for endometrial or lower urinary tract (including bladder) biopsy by aspiration with a syringe during diagnostic procedures. Generally recognized indications for diagnostic hysteroscopy include: • Abnormal bleeding • Infertility and pregnancy wastage • Evaluation of abnormal hysterosalpingogram	Hysteroscopy: The LUMINELLE DTx Hysteroscopy System is used to permit 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. When LUMINELLE DTx Hysteroscopy System is specifically used with the LUMINELLE Dx 360º Rotatable Disposable Sheath (Diagnostic), the system is limited to performing diagnostic procedures only 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 use for operative hysteroscopy include:	The Indications for Use of the LUMINELLE DTx System is the same as the Indications for Use of the primary predicate, LUMINELLE DTx Hysteroscopy System (K192278).

Item	Subject Device LUMINELLE DTx System	Predicate Device LUMINELLE DTx Hysteroscopy System (K192278)	Comparison
	• Intrauterine foreign body • Amenorrhea • Pelvic pain Generally recognized indications for use for operative hysteroscopy include: • Directed endometrial biopsy • Polypectomy • Submucous myomectomy • Transection of intrauterine adhesions • Transection of intrauterine septa • Endometrial ablation Cystoscopy: The LUMINELLE DTx 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. NOTE: When LUMINELLE DTx System is specifically used with the LUMINELLE Dx 360º Rotatable Disposable Sheath (Diagnostic), the system is limited to performing diagnostic procedures only.	• 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. NOTE: When LUMINELLE DTx Hysteroscopy System is specifically used with the LUMINELLE Dx 360º Rotatable Disposable Sheath (Diagnostic), the system is limited to performing diagnostic procedures only.	

Item	Subject Device LUMINELLE DTx System	Predicate Device LUMINELLE DTx Hysteroscopy System (K192278)	Comparison
	NOTE: When the LUMINELLE DTx System is used with the LUMINELLE Bx 360° Rotatable Disposable Sheath (Biopsy), the system is limited to performing diagnostic procedures only. The Bx Sheath can be used for endometrial or lower urinary tract (including bladder) biopsy by aspiration with a syringe during diagnostic procedures.		
Intended Use	**Hysteroscopy Intended Use:** The LUMINELLE DTx System is used to permit direct viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic and surgical procedures. NOTE: When LUMINELLE DTx System is specifically used with the LUMINELLE Dx 360º Rotatable Disposable Sheath (Diagnostic), the system is limited to performing diagnostic procedures only. **Cystoscopy Intended Use:** The LUMINELLE DTx System is intended for use in endoscopic access to the 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. NOTE: When LUMINELLE DTx System is specifically used with the LUMINELLE Dx 360º Rotatable Disposable Sheath (Diagnostic), the	**Hysteroscopy Intended Use:** 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: When LUMINELLE DTx Hysteroscopy System is specifically used with the LUMINELLE Dx 360º Rotatable Disposable Sheath (Diagnostic), the system is limited to performing diagnostic procedures only. **Cystoscopy Intended Use:** The LUMINELLE DTx Hysteroscopy System is intended for use in endoscopic access to the 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. NOTE: When LUMINELLE DTx Hysteroscopy System is specifically used with the LUMINELLE Dx 360º Rotatable Disposable	The Intended Use of the LUMINELLE DTx System is the same as the Intended Use of the Primary predicate, LUMINELLE DTx Hysteroscopy System (K192278).

Item	Subject Device LUMINELLE DTx System	Predicate Device LUMINELLE DTx Hysteroscopy System (K192278)	Comparison
	system is limited to performing diagnostic procedures only. NOTE: When the LUMINELLE DTx System is used with the LUMINELLE Bx 360° Rotatable Disposable Sheath (Biopsy), the system is limited to performing diagnostic procedures only. The Bx Sheath can be used for endometrial or lower urinary tract (including bladder) biopsy by aspiration with a syringe during diagnostic procedures.	Sheath (Diagnostic), the system is limited to performing diagnostic procedures only.	
Product Code	HIH (Hysteroscope and Accessories) FAJ (Cystoscope and Accessories)	HIH (Hysteroscope and Accessories) FAJ (Cystoscope and Accessories)	The Product Codes of the LUMINELLE DTx System are identical to the product codes of the primary predicate, LUMINELLE DTx Hysteroscopy System (K192278).
Patient Contacting Materials (Biocompatibility)	ISO 10993 Compliant	ISO 10993 Compliant	The biocompatibility compliance of patient contacting materials of the LUMINELLE DTx System is identical to the compliance of the primary predicate, LUMINELLE DTx Hysteroscopy System (K192278).
Components	• LUMINELLE DTx Hysteroscope • LUMINELLE DTx 360° Rotatable Disposable Sheath	• LUMINELLE DTx Hysteroscope • LUMINELLE DTx 360° Rotatable Disposable Sheath	The main components of the LUMINELLE DTx System are identical to the main components of the primary predicate,

Item	Subject Device LUMINELLE DTx System	Predicate Device LUMINELLE DTx Hysteroscopy System (K192278)	Comparison
	• LUMINELLE DTx 360° Rotatable Disposable Sheath Rigid • LUMINELLE Communication Cable • LUMINELLE Control Hub • LUMINELLE Dx 360° Rotatable Disposable Sheath (Diagnostic) • LUMINELLE Bx 360° Rotatable Disposable Sheath (Sheath)	• LUMINELLE DTx 360° Rotatable Disposable Sheath Rigid • LUMINELLE Communication Cable • LUMINELLE Control Hub • LUMINELLE Dx 360° Rotatable Disposable Sheath (Diagnostic)	LUMINELLE DTx Hysteroscopy System (K192278). The only difference is the addition of a new accessory, LUMINELLE Bx 360° Rotatable Disposable Sheath (Biopsy). This difference does not affect the safety and effectiveness of the device as validation and verification has been performed on the new sheath.
Rigid/Flexible Sheath	Flexible and rigid sheaths available: • Flexible sheath (LUMINELLE DTx 360° Rotatable Disposable Sheath) contains a PEEK (polyetheretherketone) hypotube for flexibility. • Rigid sheath (LUMINELLE DTx 360° Rotatable Disposable Sheath Rigid, LUMINELLE Dx 360° Rotatable Disposable Sheath (Diagnostic) and LUMINELLE Bx 360° Rotatable Disposable Biopsy Sheath) contains a 304 stainless steel inner tube for rigidity.	Flexible and rigid sheaths available: • Flexible sheath (LUMINELLE DTx 360° Rotatable Disposable Sheath) contains a PEEK (polyetheretherketone) hypotube for flexibility. • Rigid sheath (LUMINELLE DTx 360° Rotatable Disposable Sheath Rigid and LUMINELLE Dx 360° Rotatable Disposable Sheath (Diagnostic)) contains a 304 stainless steel inner tube for rigidity	The LUMINELLE DTx System is substantially equivalent to the primary predicate, LUMINELLE DTx Hysteroscopy System (K192278), as they both contain rigid and flexible sheaths.

Item	Subject Device LUMINELLE DTx System	Predicate Device LUMINELLE DTx Hysteroscopy System (K192278)	Comparison
Sheath Channels	**LUMINELLE DTx 360° Rotatable Disposable Sheath and LUMINELLE DTx 360° Rotatable Disposable Sheath Rigid** - 4 Channels; one for the scope, two for fluid management, and one for operative instruments. **LUMINELLE Dx 360° Rotatable Disposable Sheath (Diagnostic) and LUMINELLE Bx 360° Rotatable Disposable Sheath (Biopsy)** - 2 Channels that merge into a single channel; one for the scope and one for fluid management that merge through a funnel to become a single channel.	**LUMINELLE DTx 360° Rotatable Disposable Sheath and LUMINELLE DTx 360° Rotatable Disposable Sheath Rigid** - 4 Channels; one for the scope, two for fluid management, and one for operative instruments. **LUMINELLE Dx 360° Rotatable Disposable Sheath (Diagnostic)** - 2 Channels that merge into a single channel; one for the scope and one for fluid management that merge through a funnel to become a single channel.	The sheath channels of the LUMINELLE DTx System of the LUMINELLE Bx 360° Rotatable Disposable Sheath (Biopsy) are identical to the LUMINELLE Dx 360° Rotatable Disposable Sheath (Diagnostic) of the primary predicate device, LUMINELLE DTx Hysteroscopy System (K192278).
Syringes during Biopsy Procedure	For biopsy procedures, a 10 mL Luer Lock syringe is attached to the sheath	Not applicable	The LUMINELLE DTx System is substantially equivalent to the primary predicate, LUMINELLE DTx Hysteroscopy System (K192278). The only difference is the addition of the Bx adapter that enables a syringe to be connected via a luer lock. This difference does not affect the safety and effectiveness of the device as validation and verification has been performed on the new sheath.
Images	Devices can take and transmit images	Device can take and transmit images	The LUMINELLE DTx System is identical to the primary predicate device, LUMINELLE DTx Hysteroscope System

Item	Subject Device LUMINELLE DTx System	Predicate Device LUMINELLE DTx Hysteroscopy System (K192278)	Comparison
			(K192278), as the device can take and transmit images.
Scope Working Length	240 mm	240 mm	The scope working length of the LUMINELLE DTx System is identical to the scope working length of the primary predicate, LUMINELLE DTx Hysteroscopy System (K192278).
Image Processing and Display	Image Processing: Digital Video Processor Display: Standard HD Monitor/TV.	Image Processing: Digital Video Processor Display: Standard HD Monitor/TV.	The image processing and display of the LUMINELLE DTx System is identical to the image processing and display of the primary predicate, LUMINELLE DTx Hysteroscopy System (K192278).
Objective Lens • **Focal Length** • **Field of View** • **Direction of View**	Focal Length: 5 – 50 mm Field of View: 120° in air Direction of View: Forward (0°)	Focal Length: 5 – 50 mm Field of View: 120° in air Direction of View: Forward (0°)	The objective lens of the LUMINELLE DTx System is identical to the objective lens of the primary predicate, LUMINELLE DTx Hysteroscopy System (K192278).
Image Resolution	CMOS chip is 400 x 400 pixels. USAF 1951 bar code Group-Element: 1-5	CMOS chip is 400 x 400 pixels. USAF 1951 bar code Group-Element: 1-5	The image resolution of the LUMINELLE DTx System is identical to the image resolution of the primary predicate, LUMINELLE DTx Hysteroscopy System (K192278).

Item	Subject Device LUMINELLE DTx System	Predicate Device LUMINELLE DTx Hysteroscopy System (K192278)	Comparison
Power Requirements	120V AC	120V AC	The power requirements of the LUMINELLE DTx System are identical to the power requirements of the primary predicate, LUMINELLE DTx Hysteroscopy System (K192278).
Power Supply	LUMINELLE Control Hub includes the power supply which converts 120V AC to 12V DC. The Control Hub also serves as the image converter and visualization connection.	LUMINELLE Control Hub includes the power supply which converts 120V AC to 12V DC. The Control Hub also serves as the image converter and visualization connection.	The power supply of the LUMINELLE DTx System is identical to the power supply of the primary predicate, LUMINELLE DTx Hysteroscopy System (K192278).
Cables	LUMINELLE Communication Cable which powers the Scope from the Control Hub and transmits the image, HDMI and USB cables for connection of the Control Hub to a monitor or computer	LUMINELLE Communication Cable which powers the Scope from the Control Hub and transmits the image, HDMI and USB cables for connection of the Control Hub to a monitor or computer	The cables of the LUMINELLE DTx System are identical to the primary predicate, LUMINELLE DTx Hysteroscopy System (K192278).
Mode of Operation	Continuous	Continuous	The mode of operation of the LUMINELLE DTx System is identical to the mode of operation primary predicate, LUMINELLE DTx Hysteroscopy System (K192278).
Electrical Safety	Compliant with requirements of IEC 60601-1; IEC 60601-2-18	Compliant with requirements of IEC 60601-1; IEC 60601-2-18	The electrical safety compliance of the LUMINELLE DTx System is identical to the electrical safety compliance of the primary predicate,

Item	Subject Device LUMINELLE DTx System	Predicate Device LUMINELLE DTx Hysteroscopy System (K192278)	Comparison
			LUMINELLE DTx Hysteroscopy System (K192278).
Thermal Safety	Compliant with requirements of IEC 60601-1; IEC 60601-2-18	Compliant with requirements of IEC 60601-1; IEC 60601-2-18	The thermal safety compliance of the LUMINELLE DTx System is identical to the thermal safety compliance of the primary predicate, LUMINELLE DTx Hysteroscopy System (K192278).
Electromagnetic Compatibility	Compliant with requirements of: IEC 60601-1-2 4th edition	Compliant with requirements of: IEC 60601-1-2 4th edition	The electromagnetic compatibility compliance of the LUMINELLE DTx System is identical to that of the primary predicate, LUMINELLE DTx Hysteroscopy System (K192278).
Degree of Protection Against Electrical Shock	Type BF	Type BF	The degree of protection against electrical shock of the LUMINELLE DTx Hysteroscopy System is identical to the degree of protection against electrical shock of the primary predicate, LUMINELLE DTx Hysteroscopy System (K192278).
Degree of Protection	IPX7	IPX7	The degree of protection against invasion of liquids of the LUMINELLE DTx System is

Item	Subject Device LUMINELLE DTx System	Predicate Device LUMINELLE DTx Hysteroscopy System (K192278)	Comparison
Against Invasion of Liquids			identical to the degree of protection against invasion of liquids of the primary predicate, LUMINELLE DTx Hysteroscopy System (K192278)
Site of Use	Hospitals and Physician offices	Hospitals and Physician offices	The LUMINELLE DTx System is identical to the primary predicate, LUMINELLE DTx Hysteroscopy (K192278) as they are both used in hospitals and physician offices.
Reprocessing	No reprocessing required on the sheaths - the LUMINELLE DTx 360° Rotatable Disposable Sheath, LUMINELLE DTx 360° Rotatable Disposable Sheath Rigid, LUMINELLE Dx 360° Rotatable Disposable Sheath (Diagnostic), and LUMINELLE Bx 360° Rotatable Disposable Biopsy Sheath and are single-use disposable and are provided sterile.	No reprocessing required on the sheaths - the LUMINELLE DTx 360° Rotatable Disposable Sheath, LUMINELLE DTx 360° Rotatable Disposable Sheath Rigid, and LUMINELLE Dx 360° Rotatable Disposable Sheath (Diagnostic) are single-use disposable and are provided sterile.	The reprocessing of the sheaths of the LUMINELLE DTx System is identical to the sheath reprocessing of the primary predicate, LUMINELLE DTx Hysteroscopy System (K192278), as they are both intended for single-use.
Sterilization Cycles	Andersen Scientific Standard Ethylene Oxide (EO) Flexible Bag Process Steris V-PRO Low Temperature Sterilization	Andersen Scientific Standard Ethylene Oxide (EO) Flexible Bag Process	The sterilization of the LUMINELLE DTx system is substantial equivalent to the primary predicate, LUMINELLE DTx Hysteroscope System (K192278), as they both use an Ethylene Oxide Cycle. However, the LUMINELLE DTx System uses an additional cycle, Steris V-PRO Low Temperature Sterilization, for sterilization.

Item	Subject Device LUMINELLE DTx System	Predicate Device LUMINELLE DTx Hysteroscopy System (K192278)	Comparison
			This difference was validated and tested to ensure that this sterilization cycle does not affect the safety and effectiveness of the device.
High Level Disinfectants (intended for cystoscopy procedures only for High Level Disinfection)	0.6% ortho-Phthalaldehyde (OPA) Steris Revital-Ox™ RESERT High Level Disinfectant	0.6% ortho-Phthalaldehyde (OPA)	The High Level Disinfectants of the LUMINELLE DTx system is substantial equivalent to the primary predicate, LUMINELLE DTx Hysteroscope System (K192278), as they both use an 0.6% ortho-Phthalaldehyde (OPA). However, the LUMINELLE DTx System uses an additional disinfectant, Steris Revital-Ox™ RESERT High Level Disinfectant, for high level disinfection. This difference was validated and tested to ensure that this sterilization cycle does not affect the safety and effectiveness of the device.

Testing

LUMINELLE DTx System was verified and validated in accordance with documented Verification & Validation plans and protocols to ensure conformance with established performance criteria. See below for the type of tests performed. completed the following testing:

Performance - Bench

- Design verification and validation of the LUMINELLE DTx System included useful life testing following multiple cycles of high-level cleaning and disinfection, functional performance testing after accelerated aging in accordance with ASTM F1980-16, durability of the reusable handle markings following multiple cycles of high-level cleaning and disinfection, and shipping and handling simulation for the reusable components of the system.

- Design validation testing of the LUMINELLE DTx System included usability testing in accordance with IEC 62366-1 and ANSI/AAMI HE75 in simulated uterine and bladder models. Instructions for Use were also evaluated by the physicians during the design validation testing. The reprocessing instructions were validated for use by Sterile Processing Department technicians.

- Design validation testing was performed for the LUMINELLE DTx System with the LUMINELLE Bx 360° Rotatable Disposable Sheath (Biopsy) to confirm that the sheath performs according to its intended use in *in vivo* models, the user is able to operate the system as intended, and the sheath conforms to user needs.

- Bench testing was performed on the LUMINELLE Bx 360° Rotatable Disposable Sheath (Biopsy) to confirm that the sheath performs as expected

Software Validation

- Software verification and validation testing of the LUMINELLE DTx System was performed for its software component.

Reprocessing

- Validation of the cleaning and high-level disinfection procedures was performed in accordance with the FDA guidance document "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling - Guidance for Industry and Food and Drug Administration Staff, Document issued on: March 17, 2015".

- Validation of the Steris V-PRO® Low Temperature Sterilization cycle and was performed for reprocessing of the LUMINELLE DTx Scope in accordance with the FDA guidance document "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling - Guidance for Industry and Food and Drug Administration Staff, Document issued on: March 17, 2015".

- Validation of the Steris Revital-Ox™ RESERT® High Level Disinfectant for High Level Disinfection was performed for reprocessing of the LUMINELLE DTx Scope per the FDA guidance document "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling - Guidance for Industry and Food and Drug Administration Staff, Document issued on: March 17, 2015".

Biocompatibility

- The biocompatibility of the patient contacting materials of the sterile, single-use 360º Rotatable Disposable Sheath and insertion tube of the reusable LUMINELLE DTx Scope was established in accordance with ISO 10993-1. The results of biocompatibility testing confirmed that the materials of the 360º Rotatable Disposable Sheath and insertion tube are not cytotoxic, sensitizing, or irritating when in contact with human skin. Sensitization and irritation testing, was also performed for the LUMINELLE Dx 360° Rotatable Disposable Sheath (Diagnostic) in accordance with ISO 10993-10:2016 to confirm that the sheath does not induce sensitization or irritation. Cytotoxicity testing was performed for the LUMINELLE Dx 360° Rotatable Disposable Sheath (Diagnostic) in accordance with ISO 10993-5:2009 to confirm that the sheath does not induce cytotoxicity.

Electromagnetic Compatibility / Electrical Safety:

- The LUMINELLE DTx System was tested and found to be compliant with the following standards for electrical safety and EMC: IEC 60601-1, IEC 60601-1-6, IEC 60601-2-18 and IEC 60601-1-2.

- The LUMINELLE DTx System was tested and found to be compliant with the following standards for medical endoscopes: ISO 8600-1, ISO 8600-3, ISO 8600-4 and ISO 8600-5.

Shelf-Life

To verify the shelf life of the disposable sheaths, the LUMINELLE DTx 360° Rotatable Disposable Sheath was sterilized using an established 100% Ethylene Oxide (EO) sterilization process in accordance with ISO 11135:2014, with a Sterility Assurance Level (SAL) of 10^{-6}. An initial shelf life of one (1) year for the sterile packaging was verified by leak testing in accordance with ASTM F2096-11 and seal strength testing in accordance with ASTM F88-15 following accelerated aging in accordance with ASTM F1980-16. Following EO sterilization and environmental conditioning in accordance with ISTA 2A (2011), simulated distribution testing was conducted in accordance with ASTM D4169-16, Distribution Cycle 13 (intercity air/local motor freight), Assurance Level 1, Schedules: A, C, F, E, J, and A. Subsequent leak testing and seal strength testing demonstrated that the packaging maintained a sterile barrier throughout the normal transportation and distribution of the device.

- Additional testing occurred in K192278 as an accelerated-aging shelf-life study was performed for packaged LUMINELLE Dx 360° Rotatable Disposable Sheath (Diagnostic) to confirm the thirteen-month (13) shelf life of the sheaths. After accelerating aging in accordance with ASTM F1980-16, visual inspection was performed to inspect for product damage caused by the aging process, and functional design verification was performed to verify that the documented inputs met the documented outputs.

- Accelerated aging was performed on the LUMINELLE Bx 360° Rotatable Disposable Sheath (Biopsy) for a thirteen (13) month period in accordance with ASTM F1980-16. After aging was complete, visual inspection was performed to inspect for product damage caused by the aging process, and functional design verification was performed to verify that the documented inputs met the documented outputs of the device.

Distribution / Transit

- Distribution simulation testing in accordance with ASTM D4169-16, Distribution Cycle 13; Assurance Level I was performed for the LUMINELLE Dx 360° Rotatable Disposable Sheath (Diagnostic). This testing consisted of seal strength testing in accordance with ASTM F88-15 and bubble leak testing in accordance with ASTM F2096-11 to confirm that the packaging maintained a sterile barrier throughout the normal transportation and distribution of the device.

Sterilization

- A sterilization adoption evaluation was performed for the LUMINELLE Dx 360° Rotatable Disposable Sheath in accordance with AAMI TIR28:2016. Product adoption and process equivalence for Ethylene Oxide (EO) Sterilization to confirm that the previously performed sterilization validation is also applicable to the LUMINELLE Dx 360° Rotatable Disposable Sheath. The evaluation confirmed that the differences between the LUMINELLE Dx 360° Rotatable Disposable Sheath and the validated product are insignificant. Bioburden, microorganism characterization, and EO residuals testing was performed to substantiate the rationale leading to the conclusion that the changes are minor.

- A sterilization adoption evaluation was performed for the LUMINELLE Bx 360° Rotatable Disposable Sheath (Biopsy) in accordance with AAMI TIR28:2016. Product adoption and process equivalence for Ethylene Oxide (EO) Sterilization to confirm that the previously performed sterilization validation is also applicable to the LUMINELLE Bx 360° Rotatable Disposable Sheath (Biopsy). The evaluation confirmed that the differences between the LUMINELLE Bx 360° Rotatable Disposable Sheath (Biopsy) and the validated product are insignificant. To substantiate the rationale leading to the conclusion that the changes are minor, bioburden, microorganism characterization, and EO residuals testing was performed

Substantial Equivalence Discussion

The intended use for LUMINELLE DTx System is the same as that of the previously cleared LUMINELLE DTx Hysteroscope System (K192278). The technological characteristics of the LUMINELLE DTx System are different from the LUMINELLE DTx Hysteroscope System (K192278) in that the LUMINELLE DTx System includes the LUMINELLE Bx 360° Rotatable Disposable Sheath (Biopsy). However, this difference does not raise different questions of safety and effectiveness. Performance testing shows that the LUMINELLE DTx System is as safe and effective as the previously cleared LUMINELLE DTx Hysteroscopy System (K192278).

Conclusion

The LUMINELLE DTx System is substantially equivalent to the legally marketed predicate device K192278.