November 1, 2019

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

Re: K192278
Trade/Device Name: LUMINELLE DTx Hysteroscopy System
Regulation Number: 21 CFR 884.1690
Regulation Name: Hysteroscope And Accessories
Regulatory Class: II
Product Code: HIH, FAJ
Dated: September 26, 2019
Received: October 2, 2019

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,

Sharon Andrews
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K192278

Device Name

LUMINELLE DTx Hysteroscopy System

Indications for Use *(Describe)*

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 360 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:
• 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 360 Rotatable Disposable Sheath (Diagnostic), the system is limited to performing diagnostic procedures only.

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

UVision360 Inc.

This 510(k) Summary is in conformance with 21CFR 807.92

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: October 9, 2019

Device Name and Classification

Trade Name: LUMINELLE DTx Hysteroscopy 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
Classification Panel: Obstetrics/Gynecology
Gastroenterology/Urology
Product Code: HIH Hysteroscope (And Accessories)
FAJ Cystoscope And Accessories; Flexible/Rigid

Predicate Device:

	Predicate Device
Trade Name	LUMINELLE DTx Hysteroscopy System
Common Name	Hysteroscope (and accessories); Cystoscope (and accessories)
510(k) Submitter / Holder	UVision360 Inc.
510(k) Number	K190827
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 Hysteroscopy 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 360^0 Rotatable Disposable Sheath Rigid to the system (K190827).

Based on user feedback for a thinner option for the disposable sheath for only diagnostic use, UVision360, Inc. (hereafter UVision) proposes the addition of a new accessory, the LUMINELLE Dx 360° Rotatable Disposable Sheath (Diagnostic), as part of an engineering performance change.

The LUMINELLE DTx Hysteroscopy System indications for use is identical to the previously cleared indications for use for the system. However, when the system is used with the LUMINELLE Dx 360° Rotatable Disposable Sheath (Diagnostic), the indications for use are limited to diagnostic use only.

No changes are proposed for the previously cleared components of the LUMINELLE DTx Hysteroscopy System. The new LUMINELLE Dx 360° Rotatable Disposable Sheath (Diagnostic) accessory is a modification of the LUMINELLE DTx 360° Rotatable Disposable Sheath Rigid component of the previously cleared LUMINELLE DTx Hysteroscopy System (K190827) with the following main changes:

- The new accessory has one fluid line rather than the two fluid lines of the previously cleared component.
- The new accessory has a combined channel for the scope and the fluid line rather than the separate channels of the previously cleared component.
- The new accessory has no operative channel available unlike the previously cleared component, due to the fact that it is for diagnostic use only.

Indications for Use

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 360^o 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:

- 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.

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

Detailed Comparison of the Subject and Predicate Devices

Item	Subject Device LUMINELLE DTx Hysteroscopy System	Predicate Device LUMINELLE DTx Hysteroscopy System (K190827)	Comparison
	General		
Indications for Use	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.	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. Generally recognized indications for diagnostic hysteroscopy include: • Abnormal bleeding • Infertility and pregnancy wastage • Evaluation of abnormal hysterosalpingogram • Intrauterine foreign body • Amenorrhea • Pelvic Pain	The Indications for Use of the LUMINELLE DTx Hysteroscopy System are identical to the Indications for Use of the previously cleared LUMINELLE DTx Hysteroscopy System (K190827), except that when 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 Hysteroscopy System	Predicate Device LUMINELLE DTx Hysteroscopy System (K190827)	Comparison
	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 Hysteroscopy System is intended for use in endoscopic access to	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 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.	

Item	Subject Device LUMINELLE DTx Hysteroscopy System	Predicate Device LUMINELLE DTx Hysteroscopy System (K190827)	Comparison
	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.		
Intended Use	**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	**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. **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	The Intended Use of the LUMINELLE DTx Hysteroscopy System is identical to the Intended Use of the previously cleared LUMINELLE DTx Hysteroscopy System (K181909), except that when specifically used with the LUMINELLE Dx 360º Rotatable Disposable Sheath (Diagnostic), the

Item	Subject Device LUMINELLE DTx Hysteroscopy System	Predicate Device LUMINELLE DTx Hysteroscopy System (K190827)	Comparison
	LUMINELLE Dx 360º Rotatable Disposable Sheath (Diagnostic), the system is limited to performing diagnostic procedures only. **<u>Cystoscopy Intended Use:</u>** 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 Sheath (Diagnostic), the system is limited to performing diagnostic procedures only.	bladder. When combined with accessory instruments, the System allows the user to perform various diagnostic and therapeutic procedures.	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 Hysteroscopy System are identical to the product codes of the previously

Item	Subject Device LUMINELLE DTx Hysteroscopy System	Predicate Device LUMINELLE DTx Hysteroscopy System (K190827)	Comparison
			cleared LUMINELLE DTx Hysteroscopy System (K190827).
Patient Contacting Materials (Biocompatibility)	ISO 10993 Compliant	ISO 10993 Compliant	The biocompatibility compliance of patient contacting materials of the LUMINELLE DTx Hysteroscopy System is identical to the compliance of the previously cleared LUMINELLE DTx Hysteroscopy System (K190827).
Components	• LUMINELLE DTx Hysteroscope • LUMINELLE DTx 360° Rotatable Disposable Sheath • LUMINELLE DTx 360° Rotatable Disposable Sheath Rigid • LUMINELLE Communication Cable • LUMINELLE Control Hub • LUMINELLE Dx 360° Rotatable Disposable Sheath (Diagnostic)	• LUMINELLE DTx Hysteroscope • LUMINELLE DTx 360° Rotatable Disposable Sheath • LUMINELLE DTx 360° Rotatable Disposable Sheath Rigid • LUMINELLE Communication Cable • LUMINELLE Control Hub	The main components of the LUMINELLE DTx Hysteroscopy System are mainly the same as the main components of the previously cleared LUMINELLE DTx Hysteroscopy System (K190827). The only difference is the addition of a new accessory. This difference only limits the intended use and does not raise different questions of safety and effectiveness.

Item	Subject Device LUMINELLE DTx Hysteroscopy System	Predicate Device LUMINELLE DTx Hysteroscopy System (K190827)	Comparison
			This difference does not alter the intended use.
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 and LUMINELLE Dx 360° Rotatable Disposable Sheath (Diagnostic)) 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) contains a 304 stainless steel inner tube for rigidity.	The rigidity of the LUMINELLE DTx Hysteroscopy System is identical to the rigidity of the LUMINELLE DTx 360° Rotatable Diagnostic Sheath Rigid of the previously cleared LUMINELLE DTx Hysteroscopy System (K190827).
Sheath manipulation	Rotatable sheath with a curved tip	Rotatable sheath with a curved tip	The sheath manipulation of the LUMINELLE DTx Hysteroscopy System is identical to the sheath manipulation of the previously cleared LUMINELLE DTx Hysteroscopy System (K190827).

Item	Subject Device LUMINELLE DTx Hysteroscopy System	Predicate Device LUMINELLE DTx Hysteroscopy System (K190827)	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)** - 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.	4 Channels; one for the scope, two for fluid management, and one for operative instruments.	The sheath channels of the LUMINELLE DTx Hysteroscopy System are different from the sheath channels of the previously cleared LUMINELLE DTx Hysteroscopy System (K190827). This difference only limits the intended use and does not raise different questions of safety and effectiveness. This difference does not alter the intended use.
Instrument Channel Diameter	**LUMINELLE DTx 360° Rotatable Disposable Sheath and LUMINELLE DTx 360° Rotatable Disposable Sheath Rigid** – 5 Fr (1.7 mm) **LUMINELLE Dx 360° Rotatable Disposable Sheath (Diagnostic)** - Not applicable. There is no instrument channel.	5 Fr. (1.7 mm)	There is no instrument channel in the LUMINELLE DTx Hysteroscopy System compared to the 5 Fr. instrument channel diameter of the previously cleared LUMINELLE DTx Hysteroscopy System (K190827). This difference only limits the intended use and does not raise different

Item	Subject Device LUMINELLE DTx Hysteroscopy System	Predicate Device LUMINELLE DTx Hysteroscopy System (K190827)	Comparison
			questions of safety and effectiveness. This difference does not alter the intended use.
Sheath Fluid Management	**LUMINELLE DTx 360° Rotatable Disposable Sheath and LUMINELLE DTx 360° Rotatable Disposable Sheath Rigid** – 2 fluid channels (inflow and outflow), with manual manipulation of fluid flow by attaching gravity-fed or pressurized bag of distending medium **LUMINELLE Dx 360° Rotatable Disposable Sheath (Diagnostic)** - 1 fluid channel (inflow), with manual manipulation of fluid flow by attaching gravity-fed or pressurized bag of distending medium	2 fluid channels (inflow and outflow), with manual manipulation of fluid flow by attaching gravity-fed or pressurized bag of distending medium	The sheath fluid management of the LUMINELLE DTx Hysteroscopy System is different from that of the previously cleared LUMINELLE DTx Hysteroscopy System (K190827). This difference only limits the intended use and does not raise different questions of safety and effectiveness. This difference does not alter the intended use.
Sheath Reprocessing	No reprocessing required - the LUMINELLE DTx 360° Rotatable Disposable Sheath, LUMINELLE DTx 360° Rotatable Disposable Sheath	No reprocessing required - the LUMINELLE DTx 360° Rotatable Disposable Sheath and LUMINELLE DTx 360° Rotatable Disposable Sheath Rigid are	The sheath reprocessing of the LUMINELLE DTx Hysteroscopy System is identical to the sheath reprocessing of the

Item	Subject Device LUMINELLE DTx Hysteroscopy System	Predicate Device LUMINELLE DTx Hysteroscopy System (K190827)	Comparison
	Rigid, and LUMINELLE Dx 360° Rotatable Disposable Sheath (Diagnostic) are single-use disposable and are provided sterile.	single-use disposable and are provided sterile.	previously cleared LUMINELLE DTx Hysteroscopy System (K190827).
Scope and Sheath Connection	**LUMINELLE DTx 360° Rotatable Disposable Sheath and LUMINELLE DTx 360° Rotatable Disposable Sheath Rigid** - The Insertion Tube of the Scope inserts through the scope channel of the Operative Introducer Manifold and slides through the Operative Introducer Tube. The Operative Introducer tube fully inserts into the 360° RotoSheath until the components snap together. **LUMINELLE Dx 360° Rotatable Disposable Sheath (Diagnostic)** - The Insertion Tube of the Scope inserts through the scope channel of the Introducer Manifold. The Introducer Manifold snaps together with the 360° RotoSheath.	The Insertion Tube of the Scope inserts through the scope channel of the Operative Introducer Manifold and slides through the Operative Introducer Tube. The Operative Introducer tube fully inserts into the 360° RotoSheath until the components snap together.	The scope and sheath connection for the LUMINELLE DTx Hysteroscopy System is different from that of the previously cleared LUMINELLE DTx Hysteroscopy System (K190827). This difference only limits the intended use and does not raise different questions of safety and effectiveness. This difference does alter the intended use.

Testing

UVision performed the following testing of the LUMINELLE DTx Hysteroscopy System as used with the LUMINELLE Dx 360° Rotatable Disposable Sheath (Diagnostic) accessory, to ensure its continued performance, safety, and effectiveness:

- 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 Sterilization to confirm that the previously performed sterilization validation is also applicable to the LUMINELLE Dx 360° Rotatable Disposable Sheath. To substantiate the conclusion that the processes are equivalent, bioburden, microorganism characterization, and EO residuals testing was performed. Results demonstrated that the LUMINELLE Dx 360° Rotatable Disposable Sheath sterilization may be adopted into the existing validation protocol.

- An accelerated aging shelf life study was performed for packaged LUMINELLE Dx 360° Rotatable Disposable Sheath (Diagnostic) to confirm the 13 month 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. All samples met specifications after aging.

- 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. Packages were confirmed to maintain integrity following simulated distribution.

- Usability and design validation testing was repeated for the LUMINELLE DTx Hysteroscopy System with the LUMINELLE Dx 360° Rotatable Disposable Sheath (Diagnostic) 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 product conforms to user needs. Devices met predefined acceptance criteria.

- Sensitization and irritation testing was performed for the final finished 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. Results demonstrate the device is not irritating or sensitizing.

- Cytotoxicity testing was performed for the final finished LUMINELLE Dx 360° Rotatable Disposable Sheath (Diagnostic) in accordance with ISO 10993-5:2009 to confirm that the Sheath does not induce cytotoxicity. Results demonstrate the device is not cytotoxic.

Substantial Equivalence Discussion and Conclusion

The intended use for LUMINELLE DTx Hysteroscopy System is identical to the intended use of the previously cleared LUMINELLE DTx Hysteroscopy System (K190827) with only a limitation in the intended use when used with the new accessory, LUMINELLE Dx 360° Rotatable Disposable Sheath (Diagnostic). This limitation is a subset of the predicate indications, and so does not represent a new intended use. The technological characteristics of the subject LUMINELLE DTx Hysteroscopy System are different as compared to the previously cleared LUMINELLE DTx Hysteroscopy System (K190827) in that the subject device includes the LUMINELLE Dx 360° Rotatable Disposable Sheath (Diagnostic). However, the addition of this accessory does not raise different questions of safety and effectiveness. Performance testing demonstrates that the subject device, LUMINELLE DTx Hysteroscopy System, is as safe and effective as the previously cleared LUMINELLE DTx Hysteroscopy System (K190827). Therefore, the subject device, LUMINELLE DTx Hysteroscopy System, is substantially equivalent to the predicate LUMINELLE DTx Hysteroscopy System (K190827).