June 6, 2019

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

Re: K190827
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: May 6, 2019
Received: May 10, 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/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,

Sharon M. Andrews
Assistant Division 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)*
K190827

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

UVision360 Inc. K190827

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

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 4, 2019

Device Name and Classification

Trade Name: LUMINELLE DTx Hysteroscopy System
Common Name: Hysteroscope with sheath
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	Reference Device
Trade Name	LUMINELLE DTx Hysteroscopy System	Schoelly Cystoscopies/Hysteroscope and Accessories
Common Name	Hysteroscope (and accessories); Cystoscope (and accessories)	Hysteroscope and accessories
510(k) Submitter / Holder	UVision360 Inc.	Schoelly Fiberoptic GmbH
510(k) Number	K181909	K150158
Regulation Number	21 CFR 876.1500 21 CFR 884.1690	21 CFR 876.1500 21 CFR 884.1690
Classification Panel	Gastroenterology/Urology Obstetrics/Gynecology	Obstetrics/Gynecology
Product Code	FAJ, HIH	FAJ, HIH

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

Device Description

The LUMINELLE DTx Hysteroscopy System previously received 510(k) clearance (K181909) in 2018 as a hysteroscopic and cystoscopic system. To provide the user with a more rigid option for the RotoSheath and Introducer, UVision360, Inc. (hereafter UVision) proposes the addition of a new component to the system, the LUMINELLE DTx 360° Rotatable Disposable Sheath Rigid in addition to the currently available flexible Rotatable Disposable Sheath option cleared during the previous submission (K181909).

No changes are proposed for the previously cleared components or the principles of operation of the LUMINELLE DTx Hysteroscopy System. The proposed change includes only the addition of a new component which is a modification to the previously cleared flexible LUMINELLE DTx 360^0 Rotatable Disposable Sheath.

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.

The LUMINELLE DTx Hysteroscopy System is also 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.

Indications for Use

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.

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 Device

Item	Subject Device LUMINELLE DTx Hysteroscopy System	Predicate Device LUMINELLE DTx Hysteroscopy System (K181909)	Comparison
		Intended Use	
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 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 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 (K181909).

Item	Subject Device LUMINELLE DTx Hysteroscopy System	Predicate Device LUMINELLE DTx Hysteroscopy System (K181909)	Comparison
	• Intrauterine foreign body • Amenorrhea • Pelvic Pain Generally recognized indications for use for operative hysteroscopy include: • Directed endometrial biospsy • Polypectomy • Submucous myomectomy • Transection of intrauterine adhesions • Endometrial ablation Cystoscopy: The LUMINELLE DTx Hysteroscopy System is intended for use in endoscopic access and examination of the lower	Generally recognized indications for use for operative hysteroscopy include: • Directed endometrial biospsy • Polypectomy • Submucous myomectomy • Transection of intrauterine adhesions • Endometrial ablation Cystoscopy: The LUMINELLE DTx Hysteroscopy System is intended for use in endoscopic access and examination of the lower urinary tract, including the bladder. When combined with accessory instruments, the System allows the user to perform various	

Item	Subject Device LUMINELLE DTx Hysteroscopy System	Predicate Device LUMINELLE DTx Hysteroscopy System (K181909)	Comparison
	urinary tract, including the bladder. When combined with accessory instruments, the System allows the user to perform various diagnostic and therapeutic procedures.	diagnostic and therapeutic procedures.	
Technological Characteristics			
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) contains a 304 stainless steel inner tube for rigidity.	Flexible sheath only (LUMINELLE DTx 360° Rotatable Disposable Sheath), contains a PEEK (polyetheretherketone) hypotube for flexibility.	The flexibility of the LUMINELLE DTx 360° Rotatable Disposable Sheath of the LUMINELLE DTx Hysteroscopy System is identical to the flexibility of the sheath of the previously cleared LUMINELLE DTx Hysteroscopy System (K181909). The rigidity of the LUMINELLE DTx 360° Rotatable Disposable Sheath Rigid of the LUMINELLE DTx Hysteroscopy System is higher than that of the predicate Rotatable Disposable Sheath. However, this difference does not raise different questions of safety and effectiveness. The reference device, Schoelly Cystoscopes/ Hysteroscopes and Accessories (K150158) includes a rigid sheath similar to the proposed device. All other technological characteristics are the same between the subject and predicate device.

Testing

Sterility and shelf-life

LUMINELLE DTx 360° Rotatable Disposable Sheath Rigid is packaged in the same packaging as the predicate Rotatable Disposable Sheath, with the same sealing parameters. As the LUMINELLE DTx 360° Rotatable Disposable Sheath Rigid has the same dimensions as the predicate LUMINELLE DTx 360° Rotatable Disposable Sheath and the packaging materials and sealing parameters are identical, previous sterilization validation, simulated distribution and packaging shelf-life test documentation from the predicate was leveraged to support the sterilization and seal integrity of the LUMINELLE DTx 360° Rotatable Disposable Sheath Rigid.

The shelf-life of the LUMINELLE DTx 360° Rotatable Disposable Sheath Rigid of 1 year was demonstrated through pull testing on the stainless steel hypotube bond. The device was demonstrated to maintain specifications after accelerated aging.

Design validation

Design validation testing and usability testing was conducted on the LUMINELLE DTx Hysteroscopy System with the LUMINELLE DTx 360° Rotatable Disposable Sheath Rigid to confirm that the sheath performs 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. Testing was identical to that conducted on the predicate LUMINELLE DTx 360° Rotatable Disposable Sheath. The LUMINELLE DTx 360° Rotatable Disposable Sheath Rigid met all predefined acceptance criteria.

Biocompatibility

There is no difference in patient-contacting materials, manufacturing or processing between the LUMINELLE DTx 360° Rotatable Disposable Sheath Rigid and the predicate Rotatable Disposable Sheath. Therefore, biocompatibility data from the predicate was leveraged to support the biocompatibility of the LUMINELLE DTx 360° Rotatable Disposable Sheath Rigid.

Electrical Safety

Due to the additional stainless steel utilized in the LUMINELLE DTx 360° Rotatable Disposable Sheath Rigid, dielectric strength testing was conducted for the LUMINELLE DTx Rigid 360° Rotatable Disposable Sheath Rigid to confirm that the rigid sheath can withstand dielectric strength voltages in accordance with IEC 60601-1:2005/(R)2012 and A1:2012. Results of the testing were acceptable per IEC 60601-2-2 Medical electrical equipment—Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories, which is specified by IEC 60601-2-18 Particular requirements for the basic safety and essential performance of endoscopic equipment.

Substantial Equivalence Discussion

The intended use for LUMINELLE DTx Hysteroscopy System is the same as that of the previously cleared LUMINELLE DTx Hysteroscopy System (K181909). The technological characteristics of the LUMINELLE DTx Hysteroscopy System are different from the LUMINELLE DTx Hysteroscopy System (K181909) in that the LUMINELLE DTx Hysteroscopy System includes the LUMINELLE DTx 360° Rotatable Disposable Sheath Rigid, a modified version of

the LUMINELLE DTx 360° Rotatable Disposable Sheath (K181909). However, this difference does not raise different questions of safety and effectiveness. Performance testing shows that the LUMINELLE DTx Hysteroscopy System is as safe and effective as the previously cleared LUMINELLE DTx Hysteroscopy System (K181909).

Conclusion

The LUMINELLE DTx Hysteroscopy System is substantially equivalent to the legally marketed predicate device K181909.