April 7, 2026

Cogentix Medical, Inc.
Chanrasmey White
Senior Regulatory Affairs Specialist
40 Ramland Rd. S.
Orangeburg, New York 10962

Re: K253905
Trade/Device Name: PrimeSight UltraView System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FAJ, HIH
Dated: March 20, 2026
Received: March 20, 2026

Dear Chanrasmey White:

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 (the 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 available 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: The Center for Devices and Radiological Health (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, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Mark R. Kreitz -S

for Mark J. Antonino, M.S.
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253905

Device Name
PrimeSight UltraView System

Indications for Use *(Describe)*

PrimeSight UltraView® Hybrid Flexible Video Cystoscope:
Indications for Cystoscopy:
- Endoscopic access 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.

Indications for Hysteroscopy:
For accessing the cervical canal and uterine cavity for the purpose of performing diagnostic and therapeutic surgical procedures.

PrimeSight UltraView® All-in-One Video Processor Unit:
The PrimeSight UltraView® All-in-One Video Processor Unit, when used in conjunction with a Laborie flexible videoscope (i.e., UV-6000 or UV-6000i) with Slide-On® EndoSheath® Technology, is indicated for the display and management of video and images during cystoscopy and hysteroscopy 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.

510(k) Summary

This summary is submitted in accordance with 21 CFR § 807.92(a)(1).
Date Prepared: March 31, 2026

Submitter

Manufacturer Name and Address	Cogentix Medical, Inc. 40 Ramland Road South, Orangeburg, NY 10962
Contact Information	Chanrasmey White Senior Regulatory Affairs Specialist Laborie Medical Technologies 180 International Drive Portsmouth, NH 03820 USA cwhite@laborie.com
Secondary Contact	Garrett Ahlborg Senior Manager Regulatory Affairs Laborie Medical Technologies 180 International Drive Portsmouth, NH 03820 USA gahlborg@laborie.com

Device

Proprietary Name	PrimeSight UltraView® System
Common Name	Endoscope and accessories
Classification Name	Cystoscope and accessories, flexible/rigid
Product Code Associated	FAJ, HIH
Product Code Regulation	Endoscope and accessories
Description Regulation	876.1500
Number Device Class	Class II
Review Panel	Gastroenterology/Urology
Primary Predicate Device	K071127
Reference Device	K072180
Reference Device	K181292
	The predicate and reference devices have not been subject to any design-related recalls.

Device Description

The PrimeSight UltraView® System consists of the PrimeSight UltraView® All-in-One Video Processor Unit (UVP-1000) and PrimeSight UltraView® Hybrid Flexible Video Cystoscope (UV-6000 and UV-6000i) with Slide-On® EndoSheath® Technology. The PrimeSight UltraView System forms an endoscopy system utilized for the display and management of video and images during endoscopic access and examination of the lower urinary tract, including the bladder, and for accessing the cervical canal and the uterine cavity for the purpose of performing diagnostic and therapeutic surgical procedures. When combined with accessory instruments, the endoscopic system allows the user to perform various diagnostic and therapeutic procedures. The subject PrimeSight UltraView System maintains the same intended use and indications for use of its primary predicate device, the CST-2000A Flexible Hysteroscope with EndoSheath System (K071127). In addition, the subject PrimeSight UltraView System is a modification to the currently marketed PrimeSight System which includes the reference devices, the CST-5000/5000i Cystoscopes/Hysteroscopes with Slide-On® EndoSheath® Technology (K072180) and the PrimeSight UNITY 9000 Series Video Processor (K181292). Therefore, the subject device is substantially equivalent to the identified predicate and reference devices.

Indication for Use

PrimeSight UltraView® Hybrid Flexible Video Cystoscope

Indications for Cystoscopy:

- Endoscopic access 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.

Indications for Hysteroscopy:

For accessing the cervical canal and uterine cavity for the purpose of performing diagnostic and therapeutic surgical procedures.

PrimeSight UltraView® All-in-One Video Processor Unit

The PrimeSight UltraView® All-in-One Video Processor Unit, when used in conjunction with a Laborie flexible videoscope (i.e., UV-6000 or UV-6000i) with Slide-On® EndoSheath® Technology, is indicated for the display and management of video and images during cystoscopy and hysteroscopy procedures.

Comparison of Technological Characteristics with the Predicate Devices

Table 1: Comparison of Technological Characteristics with the Predicate Devices

Element of Comparison	PrimeSight UltraView® System	Primary Predicate Vision-Sciences Flexible Cystoscope with EndoSheath® System K071127	Evaluation
Indications for Use	***PrimeSight UltraView® Hybrid Flexible Video Cystoscope*** **Indications for Cystoscopy:** • Endoscopic access 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. **Indications for Hysteroscopy:** For accessing the cervical canal and uterine cavity for the purpose of performing diagnostic and therapeutic surgical procedures. ***PrimeSight UltraView® All-in-One Video Processor Unit*** The PrimeSight UltraView® All-in-One Video Processor Unit, when used in conjunction with a Laborie flexible videoscope (i.e., UV-6000 or UV-6000i) with Slide-On® EndoSheath® Technology, is indicated for the display and management of video and images during cystoscopy and hysteroscopy 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. The CST-2000A and Slide-On® EndoSheath® System is used to permit direct viewing of the cervical canal and the uterine cavity for the purpose of performing diagnostic and therapeutic/surgical procedures.	The PrimeSight UltraView System maintains the same intended use and indications for use as its primary predicate device (K071127), which is intended for cystoscopy and hysteroscopy procedures.

Element of Comparison	PrimeSight UltraView® System	Primary Predicate Vision-Sciences Flexible Cystoscope with EndoSheath® System K071127	Evaluation
Contraindications	The UltraView Cystoscope and EndoSheath should not be used to perform cystoscopy if any one of the following conditions exists: • Patients with acute infection (acute urethritis, acute prostatitis, acute epididymitis) • Patients with untreated urinary tract infection The UltraView Cystoscope and EndoSheath should not be used to perform hysteroscopy if any one of the following conditions exists: • The patient is pregnant or suspected to be pregnant • The patient's cervix cannot be properly dilated • The patient's uterus cannot be distended • The patient has acute pelvic inflammatory disease (PID) • The patient has invasive carcinoma of the cervix • The patient has had a recent uterine perforation	The CST-2000A and Slide-On EndoSheath System should not be used to perform hysteroscopy if any one of the following conditions exists. Do not perform hysteroscopy using this equipment if: • The patient is pregnant or suspected to be pregnant • The patient's cervix cannot be properly dilated • The patient's uterus cannot be distended • The patient has acute pelvis inflammatory disease (PID) • The patient has invasive carcinoma of the cervix • The patient has had a recent uterine perforation	The PrimeSight UltraView System maintains the same contraindications as its primary predicate device (K071127) for hysteroscopy. Contraindications for cystoscopy have been added, however the addition of these contraindications does not raise new questions of safety or effectiveness.

Element of Comparison	PrimeSight UltraView® System	Primary Predicate Vision-Sciences Flexible Cystoscope with EndoSheath® System K071127	Evaluation
	The digital video processors are not contraindicated for any patient population.		
System Components	UVP-1000 – Video Processor UV-6000/6000i Slide-On EndoSheath Technology Cart, Table Top, Wall Mounted	CST-2000A C2 Slide On EndoSheath System Fiberoptic light source	The primary predicate device is a fiberoptic system, whereas the subject device is a video endoscopic system that uses an electronic image transmission system to achieve its intended use. The design and performance of the subject device have been demonstrated to be equivalent to the reference devices K181292 and K072180 through bench testing. The differences in system components compared to the primary predicate device do not raise questions on safety and effectiveness.
Workflow	Cystoscopy and Hysteroscopy Procedures with a Video Processor System	Cystoscopy and Hysteroscopy Procedures with a Fiberoptic System	The primary predicate device is a fiberoptic system, whereas the subject device is a video endoscopic system that uses an electronic image transmission system to achieve its intended use. The PrimeSight UltraView System continues to support standard procedural steps and user interactions consistent with the predicate and reference devices. The design and performance of the subject device have been demonstrated to be equivalent to the reference devices K181292 and K072180 through bench testing. The differences compared to the primary predicate device

Element of Comparison	PrimeSight UltraView® System	Primary Predicate Vision-Sciences Flexible Cystoscope with EndoSheath® System K071127	Evaluation
			do not raise questions on safety and effectiveness.
Endoscope Design	UV-6000/UV-6000i Videoscope	CST-2000A Fiberscope	The design of the subject endoscopes as part of the PrimeSight UltraView System is a design change to reference device (K072180). The overall usability and handling of the endoscope have not changed. The design and performance of the subject device have demonstrated to be equivalent to the reference device (K072180) through performance testing and does not raise questions on safety and effectiveness compared to the predicate device.
Video Processor Design	UVP-1000 Video Processor: All-in-One Computer (AIO) Camera Control Unit (CCU)	N/A	The primary predicate device is a fiberoptic system, whereas the subject device is a video endoscopic system that uses an electronic image transmission system to achieve its intended use. The subject video processor and reference device (K181292) include an All-in-One (AIO) Computer and Camera Control Unit (CCU). The design and performance of the subject device have been demonstrated to be equivalent to the reference device (K181292) through bench testing. The differences compared to the primary predicate device do not raise questions on safety and effectiveness.

Element of Comparison	PrimeSight UltraView® System	Primary Predicate Vision-Sciences Flexible Cystoscope with EndoSheath® System K071127	Evaluation
Video Processor Display Technology	Utilizes In-Plane Switching (IPS) Display Technology	N/A	The primary predicate device is a fiberoptic system, whereas the subject device is a video endoscopic system that uses an electronic image transmission system to achieve its intended use. The design and performance of the subject device have been demonstrated to be equivalent to the reference device (K181292) through bench testing. The differences compared to the primary predicate device do not raise questions on safety and effectiveness.
System Image	System allows for images to be displayed during endoscopic procedures utilizing Complementary Metal-Oxide-Semiconductor (CMOS) Image Sensor.	The optical system consists of a fiberoptic glass bundle, which transmits the image from the distal end of the scope to the eyepiece, and two fiberoptic glass illumination bundles. The scope is intended for use with a standard fiberoptic light source.	The primary predicate device is a fiberoptic system, whereas the subject device is a video endoscopic system that uses an electronic image transmission system to achieve its intended use. The design and performance of the subject device have been demonstrated to be equivalent to the reference device (K181292) through bench testing. The differences compared to the primary predicate device do not raise questions on safety and effectiveness.
System Software	Unity 3.0 Developed in accordance with IEC 62304	N/A	The UNITY 3.0 software used in the PrimeSight UltraView System was developed in accordance with IEC 62304. UNITY 3.0 is based on the currently marketed UNITY 2.0 software incorporated in the reference devices K181292 and K072180. The differences compared to the

Element of Comparison	PrimeSight UltraView® System	Primary Predicate Vision-Sciences Flexible Cystoscope with EndoSheath® System K071127	Evaluation
			primary predicate device do not raise questions on safety and effectiveness.
Electrical Safety and EMC	Electrical safety and EMC testing performed per: IEC 60601-1 IEC 60601-1-2 IEC 60601-1-6 IEC-60601-2-18	N/A	Testing for Electrical Safety and Electromagnetic Compatibility (EMC) was performed in accordance with IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC-60601-2-18 identical to the Electrical Safety and EMC performed for the reference device (K181292). The differences compared to the primary predicate device do not raise questions on safety and effectiveness.
Biocompatibility	Biocompatibility testing performed per ISO 10993-1 on EndoSheath System	Biocompatibility testing performed per ISO 10993-1 on EndoSheath System	Biocompatibility of the EndoSheath System was performed according to ISO 10993-1, identical to reference device (K072180). The differences compared to the primary predicate device do not raise questions on safety and effectiveness.
Reprocessing	Endoscope: High Level Disinfection Sterilization	Endoscope: High Level Disinfection Ethylene Oxide Sterilization	The reprocessing of the subject endoscope is equivalent to the primary predicate device, utilizing validated high-level disinfection and sterilization procedures. The validated reprocessing procedures of the subject endoscope are identical to the reference device (K072180). The differences compared to the primary predicate device do not raise questions on safety and effectiveness.

Element of Comparison	PrimeSight UltraView® System	Primary Predicate Vision-Sciences Flexible Cystoscope with EndoSheath® System K071127	Evaluation
Sterility	CV EndoSheath – Ethylene Oxide Sterilized validated to SAL 10^{-6}	C2 EndoSheath – Ethylene Oxide Sterilized validated to SAL 10^{-6}	The sterility of the compatible EndoSheath is achieved using an Ethylene Oxide sterilization process validated to a sterility assurance level (SAL) of 10^{-6}, identical with the sterilization method and performance of the primary predicate and reference devices.

Non-Clinical Performance Data

The proposed device has been evaluated against the predicate and reference devices listed in the table above. Performance testing was conducted to support the determination of substantial equivalence, including assessments of reliability, usability, functional performance (including optical equivalency), packaging, and environmental stability. All testing met the predefined acceptance criteria.

The software update from UNITY 2.0 to UNITY 3.0 was developed and validated in accordance with IEC 62304. Based on the results of this validation and supporting performance testing, the software changes do not raise any questions regarding the safety or effectiveness of the subject device.

Additionally, the PrimeSight UltraView System successfully passed all testing and demonstrates compliance with applicable electrical safety and electromagnetic compatibility (EMC) standards.

Below is a summary of the non-clinical performance testing conducted, along with the corresponding standards to which the testing demonstrates compliance:

- Software
    - IEC 62304: Medical device software - Software life cycle processes
- Electrical Safety & EMC
    - IEC 60601-1: Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
    - IEC 60601-1-2: Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests
    - IEC 60601-1-6: Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
    - IEC 60601-2-18: Medical electrical equipment – Part 2: Particular requirements for the basic safety and essential performance of endoscopic equipment
- Photobiological Safety
    - IEC 62471: Photobiological safety of lamps and lamp systems
- Environmental Stability
    - ISO 9022-2: Optics and photonics — Environmental test methods
- Packaging Verification
    - ISTA 3A: Package Integrity Testing of Product Packaging Less Than 150 lb
    - ISTA 3B: Package Testing of Packaged-Products for Less-Than-Truckload (LTL) Shipment
- Optical Equivalency
    - ISO 8600-1: Endoscopes — Medical endoscopes and endotherapy devices – Part 1: General requirements
    - ISO 8600-3: Endoscopes — Medical endoscopes and endotherapy devices – Part 3: Determination of field of view and direction of view of endoscopes with optics
    - ISO 8600-5: Optics and photonics — Medical endoscopes and endotherapy devices – Part 5: Determination of optical resolution of rigid endoscopes with optics
    - ISO 12233: Digital cameras — Resolution and spatial frequency responses
- Human Factors

  - ISO 62366-1: Medical devices – Part 1: Application of usability engineering to medical devices
- Biocompatibility Assessment
  - ISO 10993-1: Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- Reprocessing Assessment
  - ISO 17664-1: Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices – Part 1: Critical and semi-critical devices
  - ISO 11135: Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices
- In addition, functional, reliability, and usability testing were performed to verify that the design outputs meet the design inputs for the PrimeSight UltraView System. All testing was completed and met the predefined acceptance criteria.

Based on this comprehensive evaluation, the subject PrimeSight UltraView System has been determined to be substantially equivalent to the primary predicate device, the CST-2000A Flexible Hysteroscope with EndoSheath System (K071127) as well as the reference devices, the CST-5000/5000i Cystoscopes/Hysteroscopes with Slide-On® EndoSheath® Technology (K072180) and the PrimeSight UNITY 9000 Series Video Processor (K181292).

Conclusion

A comprehensive evaluation of functionality, operation, user interface, and design of the PrimeSight UltraView System has been determined to be substantially equivalent to the primary predicate device, the CST-2000A Flexible Hysteroscope with EndoSheath System (K071127), as well as the reference devices, the CST-5000/5000i Cystoscopes/Hysteroscopes with Slide-On® EndoSheath® Technology (K072180) and the PrimeSight UNITY 9000 Series Video Processor (K181292). The subject device shares the same intended use and fundamental scientific technology as the predicate and reference devices. The minor differences in technological characteristics do not introduce new or different issues of safety or effectiveness, and performance testing confirms that the subject device is at least as safe and effective as the predicates. Therefore, the subject device is substantially equivalent with respect to safety and effectiveness.