November 15, 2018

Cogentix Medical, Inc.
Christa Blaisdell
Regulatory Affairs Specialist
40 Ramland Road South
Orangeburg, NY 10962

Re: K181292
Trade/Device Name: PrimeSight™ UNITY 9000 Video Processor, PrimeSight™ UNITY 9100 Video Processor
Regulation Number: 21 CFR 874.4710
Regulation Name: Esophagoscope (Flexible or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOX, FAJ, EOB, OCS, EOQ
Dated: October 15, 2018
Received: October 16, 2018

Dear Christa Blaisdell:

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 yours,

Srinivas Nandkumar -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181292

Device Name
PrimeSight™ UNITY 9000 Video Processor, PrimeSight™ UNITY 9100 Video Processor

Indications for Use *(Describe)*
The PrimeSight™ UNITY 9000 Series Video Processors, when used in conjunction with a Cogentix Medical flexible videoscope, are indicated for the display and management of video and images during trans-nasal esophagoscopy, cystoscopy, bronchoscopy and nasopharyngoscopy 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.

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510(k) Summary

General Information

Date Prepared:	September 11, 2018
Submitter Information:	Cogentix Medical, Inc. 40 Ramland Road South Orangeburg, New York, 10962
Registration Number:	2242464
Contact:	Christa Blaisdell Regulatory Affairs Specialist Cogentix Medical, Inc. Phone: 952-426-6161 Fax: 866-255-4522 Email: christa.blaisdell@cogentixmedical.com **Alternate Contact:** Nicole Boser Director, Quality and Regulatory Affairs Cogentix Medical, Inc. Phone: 952-426-6141 Fax: 866-255-4522 Email: nicole.boser@cogentixmedical.com

Device Information

Trade Name:	PrimeSight™ UNITY 9000 Video Processor, PrimeSight™ UNITY 9100 Video Processor
Common Name:	Video Processor
Classification Name:	Esophagoscope (flexible or rigid) and accessories
Regulation Number:	21 CFR 874.4710
Product Classification:	Class II
Primary Product Code:	EOX
Secondary Product Code(s):	FAJ, OCS, EOQ, EOB
Primary Predicate Device	Flexible Trans-Nasal Video Esophagoscope with Digital Video Processor and Disposable EndoSheath Systems (K072088)

Secondary Predicate Device(s)

Vision-Sciences CST-5000 Video Cystoscope with EndoSheath System (K072180)

Vision Sciences BRS-5000 Video Bronchoscope with EndoSheath System, DPU-5000/DPU-5050 Video Processor and Accessories (K091768)

Vision-Sciences ENT-5000 Video ENT Scope with EndoSheath Technology, Vision-Sciences DPU-5000/DPU-5050 Video Processor (K102733)

Device Description

The PrimeSight™ UNITY 9000 and PrimeSight™ UNITY 9100 Video Processors (herein referred to as "UNITY 9000", "UNITY 9000 Processor" or "UNITY 9000 Series Video Processors") are video processing units designed to work exclusively with the Cogentix Medical TNE-5000, CST-5000, CST-5000*i*, BRS-5100 and ENT-5000 models of flexible videoscopes (herein referred to as "5000 Series Videoscopes") to display images and videos during endoscopic procedures. The UNITY 9000 Processor consists of two modules which are physically connected with a hinge mechanism. The all-in-one computer (AIO PC) unit is used for the presentation and display of images and includes a large 19" wide screen display with an integrated touchscreen. The Camera Interface Module (CIM) base unit allows for the connection of a videoscope or camera to the Processor, as well as any endoscopic peripherals being used during the procedure, as well as image processing.

There are two different model configurations available for the UNITY 9000. These models are offered specific to the type of endoscopic procedure being performed. The Base Configuration model (UVP-9000) supports urology and bronchoscopy applications, while the Airway Configuration model (UVP-9100) offers an integrated air pump for trans-nasal esophagoscopy and a stroboscopy interface for use during Ear, Nose, and Throat (ENT) stroboscopy examinations.

Indications for Use

The PrimeSight UNITY 9000 Series Video Processors, when used in conjunction with a Cogentix Medical flexible videoscope, are indicated for the display and management of video and images during trans-nasal esophagoscopy, cystoscopy, bronchoscopy and nasopharyngoscopy procedures.

Intended Use

The PrimeSight UNITY 9000 Series Video Processors are intended to be used with a Cogentix Medical flexible videoscope to form an endoscopy system utilized for the following indications:

Cogentix Medical Flexible Videoscope	Flexible Videoscope Model Number	Endoscopy System Indication
Trans-nasal esophagoscope	TNE-5000	For the display and management of video and images during endoscopic examination of the larynx, esophagus, and gastro-esophageal junction
Cystoscope	CST-5000 CST-5000*i*	For the display and management of video and images during endoscopic examination of the lower urinary tract, including the bladder

Cogentix Medical Flexible Videoscope	Flexible Videoscope Model Number	Endoscopy System Indication
Bronchoscope	BRS-5100	For the display and management of video and images during airway management of the trachea and other major passages of the lungs and endoscopic diagnosis of the airways
Nasopharyngoscope	ENT-5000	For the display and management of video and images during endoscopic examination of the upper airway, vocal cords and/or nasal passages

Additional information regarding the indication and intended use for each compatible flexible videoscope is contained within the User Manual specific to that device.

Contraindications

There are no patient populations for which the PrimeSight UNITY 9000 Series Video Processors are contraindicated for.

Comparison to Predicate Device

Cogentix Medical, Inc. (formerly Vision-Sciences, Inc.) holds the 510(k) clearances to market the current DPU-5000 Series Video Processor as part of its video endoscopy systems. These products were cleared for market through multiple 510(k) submissions, which include: the Flexible Trans-Nasal Video Esophagoscope with Digital Video Processor and Disposable EndoSheath Systems (K072088); the CST-5000 Video Cystoscope with EndoSheath System (K072180); the BRS-5000 Video Bronchoscope with EndoSheath System, DPU-5000/DPU-5050 Video Processor and Accessories (K091768); and, the ENT-5000 Video ENT Scope with EndoSheath Technology and DPU-5000/DPU-5050 Video Processor (K102733).

There are no significant differences in the intended use, mechanical and functional performance or the functional scientific technology between the UNITY 9000 Series Processors and the predicate device (DPU-5000). Both systems provide image presentation and capture and storage of pictures; provide the ability for the operator to store files under a patient centric directory; and allow controls on the endoscope to interface with the Processor for the purposes of zoom, white balance or other basic image functions of the system. The UNITY 9000 Processor simply provides an updated mechanical design – which deals with parts obsolescence – and a new graphical interface when compared to its predicate. UNITY 9000 also introduces video capability and the ability to store images in a Digital Imaging and Communications in Medicine (DICOM) format for easier transposition to electronic medical records systems.

Summary of Testing

Bench testing and ISO standard compliance testing, as described below in *Table 1.1 – Summary of Testing*, was performed on the PrimeSight UNITY 9000 Series Video Processors. The results of this testing confirm that the UNITY 9000 Processor is safe and effective and performs in a manner making it substantially equivalent to its predicate device. Clinical data was not used to demonstrate substantial equivalence as the subject device and predicate device are so similar in design and functionality.

Table 1.1 – Summary of Testing

Category	Evaluation Test Reports	Associated Standards
Functional Performance	RPT-175-0020-VER – PrimeSight Product Requirements Verification Report RPT-175-0021-VER – PrimeSight Camera Interface Module Verification Report RPT-175-0023-VER – PrimeSight Mechanical Requirements Verification Report TR 013-18 – Usability Evaluation of UNITY 9000 Video Processor TR 006-18 – PrimeSight UNITY 9000 Gap Verification TR 020-18 – Video Processor Image Quality Performance	EN ISO 14971:2012 – Medical devices. Application of risk management to medical devices IEC 62366-1:2015 – Medical devices – Part 1: Application of usability engineering to medical devices IEC 62304:2006+A1:2015 – Medical device software – Software life cycle processes ISO 12233:2017 – Resolution and spatial frequency responses
Software	RPT-175-0022-VER – PrimeSight User Interface Software Requirements Verification Report RPT-175-0021-VER – PrimeSight Camera Interface Module Verification Report	
Environmental, Shipping and Transportation	TR 032-17 – Environment and Transport Testing of PrimeSight UNITY 9000	ISO 9022-1:2012 – Optics and photonics – Environmental test methods – Part 1: Definitions, extent of testing ISO 9022-2:2015 – Optics and photonics – Environmental test methods – Part 2: Cold, heat and humidity ISTA 3A:2008 – General Stimulation Performance Tests

Category	Evaluation Test Reports	Associated Standards
Electrical Safety and Electromagnetic Compatibility	Report Number 103144900BOX-002 – Cogentix Medical, Inc. Test Report – EMC Testing – UVP-9100 Report Number 103480453BOX-001 – Test Report – IEC 60601-1 Testing – Endoscopic Video Processor Report Number 103480453BOX-002 – Test Report – IEC 60601-1-6 Testing – Endoscopic Video Processor Report Number 103480453BOX-003 – Test Report – IEC 62304 Testing – Endoscopic Video Processor Report Number 103480453BOX-004 – Test Report – IEC 60601-2-18 Testing – Endoscopic Video Processor Report Number 103480453BOX-005 – Listing Constructional Data Report	IEC 60601-1:2005 + A1:2012 – Medical electrical equipment. General requirements for basic safety and essential performance IEC 60601-2-18:2009 – Medical electrical equipment – Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment IEC 60601-1-2:2014 – Medical electrical equipment. General requirements for basic safety and essential performance. Collateral Standard. Electromagnetic disturbances. Requirements and tests IEC 60601-1-6:2010 + A1:2013 – Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability IEC 62304:2006+A1:2015 – Medical device software – Software life cycle processes EN ISO 14971:2012 – Medical devices. Application of risk management to medical devices

Conclusion

Cogentix Medical, Inc. believes that based on the data contained in this 510(k) related to the indications for use, technological characteristics, and performance testing, the PrimeSight UNITY 9000 Series Video Processors have demonstrated substantial equivalence to their predicate device and are considered to be safe and effective.