May 14, 2026

Optim, LLC
% Pamela Papineau
Consultant
Delphi Medical Device Consulting, Inc.
5 Whitcomb Ave.
Ayer, Massachusetts 01432

Re: K254133
Trade/Device Name: ENTity USB Videoscope System
Regulation Number: 21 CFR 874.4760
Regulation Name: Nasopharyngoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOB
Dated: December 22, 2025
Received: December 22, 2025

Dear Pamela Papineau:

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: 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.

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,

JOYCE C. LIN -S

for Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental 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)*
K254133

Device Name
ENTity USB Videoscope System

Indications for Use *(Describe)*
The Optim ENTity USB Videoscope is intended to be used for oral or nasal introduction for the examination of the upper airway from the nasal passage to the vocal cords.

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

A. General Information

510(k) Sponsor	Optim, LLC
Address:	64 Technology Park Road Sturbridge, MA 01566 USA
FDA Registration #:	1218141
Regulation:	21 CFR 874.4760
Contact:	Justin Luongo, Engineering Manager
Contact Information:	Tel: 508-347-5100 Fax: 508-347-2380

B. Device Identification

Subject Device

Trade Name:	**ENTity USB Videoscope System**
Common Name:	Flexible Nasopharyngoscope
Classification Name:	Nasopharyngoscope (flexible or rigid)
Regulation:	21 CFR 874.4760
Product Code:	EOB
Device Classification:	Class II
Reviewing Panel:	Ear, Nose & Throat Devices
Indications for Use:	For oral or nasal introduction for the examination of the upper airway from the nasal passage to the vocal cords

Predicate Device

Trade Name:	**Optim ENTity WiFi Video Nasopharyngoscope System**
Common Name:	Flexible Nasopharyngoscope
Classification Name:	Nasopharyngoscope (flexible or rigid)
Regulation:	21 CFR 874.4760
Product Code:	EOB
Device Classification:	Class II
Reviewing Panel:	Ear, Nose & Throat Devices
510(k) Number:	K200609
Indications for Use:	For oral or nasal introduction for the examination of the upper airway from the nasal passage to the vocal cords

Reference Device

Trade Name:	**Mui Scientific PatCom Distal Chip Endoscope**
Common Name:	Flexible Nasopharyngoscope
Classification Name:	Nasopharyngoscope (flexible or rigid)
Regulation:	21 CFR 874.4760

Product Code:	EOB
Device Classification:	Class II
Reviewing Panel:	Ear, Nose & Throat Devices
510(k) Number:	K222587
Indications for Use:	The PatCom Distal Chip Endoscope is indicated when endoscopic visualization in the regions of the mouth, nasal cavity, and upper airway is required.

C. Device Description

The ENTity USB Videoscope System is a video nasopharyngoscopy system that includes a USB-powered flexible videoscope with an integral LED light source, and a USB power cable for connection to a personal computer. The computer, which is not part of the videoscope system, can be used to view images and/or to communicate with the videoscope. Light generated by an LED light source located in the videoscope handle is transmitted via optical fibers to the distal tip of the scope, where it illuminates the anatomy to be examined. A CMOS image sensor (camera chip) located at the distal tip of the videoscope captures still or video images in the form of electrical signals, which are transmitted, via the USB cable, to the computer. Still and/or video images may be viewed on the computer monitor or can be transmitted to an external monitor. Patient-contacting videoscope components are made from stainless steel, aluminum oxide, PEI, TPU, PEEK, rubber, and epoxy; the finished device meets appropriate biocompatibility endpoints per EN ISO 10993.

D. Indications for Use

The indications for use of the ENTity USB Videoscope (*for oral or nasal introduction for the examination of the upper airway from the nasal passage to the vocal cords*) are identical to those of the predicate Optim ENTity WiFi Video Nasopharyngoscope System, and equivalent to those of the Mui Scientific PatCom Distal Chip Endoscope (*when endoscopic visualization in the regions of the mouth, nasal cavity, and upper airway is required*).

E. Substantial Equivalence

Like the predicate Optim ENTity WiFi Video Nasopharyngoscope cleared in K200609, the Optim USB Videoscope System includes a videoscope with a flexible insertion section and an integral light source. The subject and predicate devices have the same indications for use (for oral or nasal introduction for the examination of the upper airway from the nasal passages to the vocal cords). The subject and predicate videoscopes are identical in terms of basic dimensional and optical characteristics, such as insertion tube working length, distal tip articulation, direction of view, field of view, and depth of field. The USB Videoscope's insertion tube shaft outer diameter is equivalent to that of the reference device and slightly smaller than that of the predicate (3.6 mm vs. 4 mm), which is desirable for patient comfort. The operating power requirements of the USB Videoscope are very similar to those of the reference device. The USB Videoscope has a higher

resolution (pixel count) than the predicate WiFi Videoscope.

The fundamental scientific technologies utilized in the subject ENTity USB Videoscope and the predicate ENTity WiFi Videoscope are also the same or equivalent. Both scopes have identical integrated LED light sources located in the videoscope handpiece, and both utilize CMOS (Complementary Metal Oxide Semiconductor) imaging technology, where a CMOS image sensor (camera) located at the distal tip of the videoscope captures and transmits a digital image signal through the scope, for ultimate display on a monitor.

Substantial equivalence for the ENTity USB Videoscope System has been established through comparison to legally marketed predicate and reference devices, supported by 1) comparative performance testing, and 2) additional safety and performance testing in accordance with recognized standards.

F. Comparison of Technical Characteristics with the Predicate Device

A summary of the differences between the subject and predicate devices is provided in accordance with 21 CFR 807.92(a)(6).

Feature	Optim ENTity USB Videoscope System (subject device)	Optim ENTity WiFi Videoscope System; K200609 (predicate device)	Mui Scientific PatCom Distal Chip Endoscope; K222587 (reference device)	Similarities and Differences
Common Name	Flexible Nasopharyngoscope System	Flexible Nasopharyngoscope System	Flexible Nasopharyngoscope System	Same
Classification Name	Nasopharyngoscope (flexible or rigid)	Nasopharyngoscope (flexible or rigid)	Nasopharyngoscope (flexible or rigid)	Same
Device Class	Class II	Class II	Class II	Same
Regulation	21 CFR 874.4760	21 CFR 874.4760	21 CFR 874.4760	Same
Product Code	EOB	EOB	EOB	Same
Indications for Use	The Optim ENTity USB Videoscope is intended to be used for oral or nasal introduction for the examination of the upper airway from the nasal passage to the vocal cords.	The Optim ENTity WiFi Video Nasopharyngoscope is intended to be used for oral or nasal introduction for the examination of the upper airway from the nasal passages to the vocal cords.	The PatCom Distal Chip Endoscope is indicated when endoscopic visualization in the regions of the mouth, nasal cavity, and upper airway is required.	Same
Use Environment	Hospital, clinic, medical office	Hospital, clinic, medical office	Hospital, clinic, medical office	Same
Principle of Operation	CMOS videoscope with integral LED illumination light source; USB cable provides	CMOS videoscope with integral battery and LED illumination light source; video processor	CMOS videoscope with integral LED illumination light source; USB cable	Same as reference device

Feature	Optim ENTity USB Videoscope System (subject device)	Optim ENTity WiFi Videoscope System; K200609 (predicate device)	Mui Scientific PatCom Distal Chip Endoscope; K222587 (reference device)	Similarities and Differences
	operating power to the scope and transmits image data to a PC	with user interface and image management capabilities; wired connection between videoscope and video processor	provides operating power to the scope and transmits image data to a PC	
System Components & Accessories	ENTity USB Video Nasopharyngoscope; USB Power Cable	ENTity WiFi Video Nasopharyngoscope; ENTity Video Processor with ENTity ICS Software; Active Touchscreen Monitor; Videoscope Battery Charger	PatCom Scope; USB cable	Same as reference device
Device Design - Videoscope	Flexible videoscope with integrated LED light source	Flexible videoscope with integrated LED light source	Flexible videoscope with integrated LED light source	Same
Scope Insertion Tube OD	3.6 mm	4.0 mm (distal tip) 3.8 mm (shaft)	3.65 mm (distal tip) 3.2 mm (shaft)	Equivalent to reference device
Scope Insertion Tube Length	300 mm	300 mm	340 mm	Same as predicate
Scope Internal Channel	None	None	None	Same
Scope Direction of View	0°	0°	0°	Same
Scope Field of View	85°	85°	110°	Same as predicate
Scope Distal Tip Articulation	135° up / down	135° up / down	130° up / down	Same as predicate
Scope Depth of Field	5 mm to 50 mm	5 mm to 50 mm	6 mm to 60 mm	Same as predicate
Scope Image Sensor (camera) Type	CMOS	CMOS	CMOS	Same
Resolution (pixel count)	720x720	400x400	1280x720	Equivalent to reference device
Videoscope / Light Source Power Source	Power from PC provided though USB power cable connection	Rechargeable Li-ion battery located in scope handpiece	Power from PC provided though USB power cable connection	Same as reference device
Videoscope / Light Source Operating Power	5V DC 1 – 1.5A	3.7V DC 2600mAh rechargeable battery	5V DC 0.5A	Equivalent to reference device
Illumination Light Source Type	LED	LED	LED	Same
Light Source Photobiological Safety	IEC 62471	IEC 62471	IEC 62471	Same
Scope – Computer/Video Processor Connection	Wired (USB-C cable)	Wireless (WiFi)	Wired (USB-A cable)	Equivalent to reference device
Biocompatibility	ISO 10993-1	ISO 10993-1	ISO 10993-1	Same

Feature	Optim ENTity USB Videoscope System (subject device)	Optim ENTity WiFi Videoscope System; K200609 (predicate device)	Mui Scientific PatCom Distal Chip Endoscope; K222587 (reference device)	Similarities and Differences
Scope Patient-Contacting Materials	304 stainless steel, glass, aluminum oxide, polyetherimide, thermoplastic polyurethane, polyetheretherketone, fluoroelastomer rubber, epoxy	303 stainless steel; glass; polyurethane; polyetheretherketone (PEEK); fluorocarbon rubber; epoxy	Stainless steel, thermoplastic polyurethane, acrylonitrile butadiene styrene	Equivalent; S.E. established through biocompatibility assessment and testing
Scope Reprocessing	Manual cleaning followed by High-Level Disinfection (AAMI TIR 12, AAMI TIR 30, ASTM E1837, AAMI ST91)	Manual cleaning followed by High-Level Disinfection (AAMI TIR 12, AAMI TIR 30, ASTM E1837, AAMI ST91)	Manual cleaning followed by High-Level Disinfection; optional sterilization (standards unknown)	Same as predicate
Usability	IEC 60601-1-6, IEC 62366-1	IEC 60601-1-6, IEC 62366-1	Unknown	Same as predicate
Software/Firmware	IEC 60601-1, IEC 60601-1-6, IEC 62304	IEC 60601-1, IEC 60601-1-6, IEC 62304	IEC 60601-1, IEC 60601-1-6, IEC 62304	Same
Electrical Safety & Performance	IEC 60601-1, IEC 60601-1-6, IEC 60601-2-18	IEC 60601-1, IEC 60601-1-6, IEC 60601-2-18	IEC 60601-1, IEC 60601-1-6, IEC 60601-2-18	Same
Electromagnetic Compatibility	IEC 60601-1-2	IEC 60601-1-2	IEC 60601-1-2	Same

G. Non-Clinical Performance Data

The ENTity WiFi Video Nasopharyngoscope has been tested in accordance with FDA-recognized consensus standards and guidance documents to confirm that the product meets design specifications for physical characteristics, performance, and safety.

Biocompatibility

Biocompatibility of the patient contacting materials contained in the ENTity USB Videoscope was established through evaluation and testing performed in accordance with ISO 10993-1:2009 *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process* and FDA's June 2016 guidance for the use of ISO 10993-1.

Reprocessing Validation

The ENTity USB Videoscope is a reusable device for which validated reprocessing instructions and reprocessing validation data are required in accordance with the June 9, 2017 Federal Register Notice *Medical Devices; Validated Instructions for Use and Validation Data Requirements for Certain Reusable Medical Devices in Premarket Notifications*. Detailed instructions for manual cleaning and high-level disinfection are included in the device labeling; these methods have been validated in accordance with FDA's 2015 *Guidance for Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling* and recognized technical guidelines such as AAMI TIR 12:2010, AAMI TIR 30:2011/R2016, and ASTM E1837-96.

Software

The Entity USB Videoscope System incorporates a combination of electronic components and firmware that work together to control certain system functions. Software life cycle processes comply with IEC 62304, *Medical Device Software – Software Life Cycle Processes.* Software and cybersecurity documentation are provided in accordance with FDA guidance including the FDA's 2025 *Guidance for the Content of Premarket Submissions for Device Software Functions*. Cybersecurity risks have been assessed and mitigated according to FDA's 2025 *Guidance for Cybersecurity in Medical Devices.*

Dimensional, Functional, and Performance Testing

The ENTity USB System has been tested at the component and system level to ensure that all design specifications were met; testing included endoscope dimensional and optical verifications (field of view, direction of view) per the ISO 8600 series of standards, operating temperature measurement, USB cable performance verification, camera performance evaluation (resolution, depth of field, noise and dynamic range, geometric distortion, image intensity uniformity, color performance) and system performance evaluation.

Electrical Safety and EMC

The ENTity USB System has been tested in accordance with 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 Safety – Collateral Standard: Electromagnetic Compatibility Requirements and Tests*, IEC 60601-1-6 *Medical Electrical Equipment, Part 1-6: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Usability*, and IEC 60601-2-18 *Medical Electrical Equipment, Part 2: Particular Requirements for the Safety of Endoscopic Equipment*.

Usability

The usability engineering principles contained in IEC 62366-1 *Medical Devices – Application of Usability Engineering to Medical Devices* were utilized in the design and development of the ENTity USB System. Usability has been evaluated in a user validation study designed and conducted in accordance with FDA's 2016 guidance *Applying Human Factors and Usability Engineering to Medical Devices.* Clinical image comparisons with the predicate device were conducted using an upper airway model; representative images were included in the submission.

H. Conclusion

Based on a comparison of the proposed and predicate device systems in terms of indications for use, technology, physical characteristics and performance specifications, together with the results of performance testing conducted in accordance with FDA guidance documents and recognized standards, the ENTity USB Videoscope System raises no new questions of safety and effectiveness, and is substantially equivalent to the predicate device.