January 13, 2021

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

Re: K200609
Trade/Device Name: ENTity WiFi Video Nasopharyngoscope System
Regulation Number: 21 CFR 874.4760
Regulation Name: Nasopharyngoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOB
Dated: December 4, 2020
Received: December 14, 2020

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 (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,

for Malvina B. Eydelman, M.D.
Director
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200609

Device Name

ENTity WiFi Video Nasopharyngoscope System

Indications for Use *(Describe)*

The ENTity WiFi Video Nasopharyngoscope System 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 5 – 510(k) Summary (K200609)

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:	Jenna Lipka, QA Manager
Contact Information:	Tel: 508-347-5100 Fax: 508-347-2380
Date Prepared:	12 January 2021

B. Device Identification

Subject Device

Trade Name:	**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
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:	**Karl Storz CMOS Video Rhino-Laryngoscope 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:	K103467
Indications for Use:	For endoscopic diagnosis within the nasal lumens and airway anatomy, and is intended to provide visualization via a video monitor

Reference Device

Trade Name:	**NDS Surgical Imaging, LLC ZeroWire Duo Wireless HD Video Transfer System G2 ("ZeroWire G2")**
Common Name:	Wireless Device

Classification Name:	Endoscope and accessories
Regulation:	21 CFR 876.1500
Product Code:	GCJ
Device Classification:	Class II
Reviewing Panel:	General & Plastic Surgery Devices
510(k) Number:	K151609
Indications for Use:	For the delivery of video signals from a source such as an endoscopy camera/processor, or other video source over a radio-frequency link to a ZeroWire Receiver for display of images during endoscopic and general surgical procedures

C. Device Description

The ENTity WiFi Video Nasopharyngoscope System is a complete video nasopharyngoscopy system that includes a rechargeable, battery-powered, flexible videoscope with an integral LED light source and WiFi connectivity; a video processor box that receives WiFi signals from the videoscope and provides HDMI output to a video monitor; image management and user interface software; a battery charger accessory for the videoscope; and an active touchscreen monitor accessory that can be used to view images and/or to communicate with the software user interface. Light generated by the LED light source located in the videoscope handle is transmitted through glass fiber optic bundles 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 wirelessly transmitted to the ENTity WiFi Video Processor. The video processor incorporates user interface and image management software. Still and/or video images may be viewed on the ENTity WiFi Active Touchscreen Monitor; the touchscreen features on the monitor can also be used to interact with the ENTity WiFi Video Processor.

D. Indications for Use

The indications for use of the ENTity WiFi Video Nasopharyngoscope (*for oral or nasal introduction for the examination of the upper airway from the nasal passage to the vocal cords*) and the predicate Karl Storz CMOS Video Rhino-Laryngoscope System cleared in K103467 (for endoscopic diagnosis within the nasal lumens and airway anatomy, and is intended to provide visualization via a video monitor) are the same with minor differences in wording. The indications for use for the ZeroWire G2 reference device (for the delivery of video signals from a source such as an endoscopy camera/processor, or other video source over a radio-frequency link to a ZeroWire Receiver for display of images during endoscopic and general surgical procedures) describe the same type of wireless communication found in the ENTity WiFi System.

E. Substantial Equivalence Comparison

Substantial equivalence for the ENTity WiFi Video Nasopharyngoscope System is primarily based on a comparison of design features and performance characteristics to those of the Karl Storz CMOS Video Rhino-Laryngoscope System cleared in K103467. This comparison is supported by non-clinical testing to confirm that the ENTity WiFi System meets design specifications for physical characteristics, performance, and safety. Wherever possible, test methods and acceptance criteria were based on FDA-recognized consensus standards and guidance documents. The NDS Surgical Imaging, LLC ZeroWire Duo Wireless HD Video Transfer System G2 (the "ZeroWire G2") cleared in K151609 is cited as a reference device to establish substantial equivalence of the wireless video image transmission capabilities of the ENTity WiFi Video Nasopharyngoscope System.

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	ENTity WiFi Video Nasopharyngoscope System (subject device)	Karl Storz CMOS Video Rhino-Laryngoscope System; K103467 (predicate device)	Similarities and Differences
Common Name	Flexible Nasopharyngoscope System	Flexible Nasopharyngoscope System	Same
Classification Name	Nasopharyngoscope (flexible or rigid)	Nasopharyngoscope (flexible or rigid)	Same
Device Class	Class II	Class II	Same
Regulation	21 CFR 874.4760	21 CFR 874.4760	Same
Product Code	EOB	EOB	Same
Indications for Use	For oral or nasal introduction for the examination of the upper airway from the nasal passage to the vocal cords	For endoscopic diagnosis within the nasal lumens and airway anatomy; intended to provide visualization via a video monitor	Same
Use Environment	Hospital, clinic, medical office	Hospital, clinic, medical office	Same
Principle of Operation	CMOS videoscope with integral battery and LED illumination light source; video processor with user interface and image management capabilities; WiFi data transfer between videoscope and video processor	CMOS videoscope with integral battery and LED illumination light source; video processor with user interface and image management capabilities; wired connection between videoscope and video processor	Different
System Components & Accessories	ENTity WiFi Video Nasopharyngoscope; ENTity Video Processor with ENTity ICS Software; Active Touchscreen Monitor; Videoscope Battery Charger	Karl Storz CMOS Video Rhino-Laryngoscope scope; Karl Storz C-MAC Monitor	Different
Device Design - Videoscope	Flexible videoscope with integrated LED light source	Flexible videoscope with integrated LED light source	Same
Scope Insertion Tube OD	4.0 mm (distal tip) 3.8 mm (shaft)	3.7 mm	Similar
Scope Insertion Tube Length	300 mm	300 mm	Same

Feature	ENTity WiFi Video Nasopharyngoscope System (subject device)	Karl Storz CMOS Video Rhino-Laryngoscope System; K103467 (predicate device)	Similarities and Differences
Scope Internal Channel	None	None	Same
Scope Direction of View	0°	0°	Same
Scope Field of View	85°	85°	Same
Scope Distal Tip Articulation	135° up / down	140° up / down	Similar
Scope Image Sensor (camera) Type	CMOS	CMOS	Same
Scope Power Source	Rechargeable Li-ion battery located in scope handpiece	Wired connection between videoscope and monitor	Different
Illumination Light Source Type	LED	LED	Same
Illumination Light Output (min)	6 Lumens	Unknown	Unknown
Light Source Photobiological Safety	IEC 62471	Unknown	Unknown
Video Processor Functionality	Image processing for display on monitor; wireless communication with videoscope; image management and storage	Image processing for display on monitor; image management and storage	Different
Video Processor Software Functionality	User interface; set/change scope button assignment, white balance & light output; image management	Unknown	Unknown
Scope – Video Processor Connection	Wireless (WiFi)	Wired	Different
Biocompatibility	ISO 10993-1	ISO 10993-1	Same
Scope Reprocessing	Manual cleaning followed by High-Level Disinfection (AAMI TIR 12, AAMI TIR 30, ASTM E1837)	Manual cleaning followed by High-Level Disinfection (AAMI TIR 12, AAMI TIR 30, ASTM E1837)	Same
Scope Patient-Contacting Materials	303 stainless steel; glass; polyurethane; polyetheretherketone (PEEK); fluorocarbon rubber; epoxy	Glass; metal; plastic	Similar
Electrical Safety & Scope Safety Performance	IEC 60601-1 IRC 60601-2-18	IEC 60601-1 IRC 60601-2-18	Same
Electromagnetic Compatibility	IEC 60601-1-2	IEC 60601-1-2	Same
Scope Optics	IEC 8600-x	IEC 8600-x	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 WiFi 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. The videoscope insertion tube has direct contact with the mucosal surfaces in the nasal passages and the nasopharynx; the duration of contact category according to ISO 10993-1 is "limited" (≤ 24 hours). The endoscope insertion tube was tested for cytotoxicity in accordance with ISO 10993-5:2009 *Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity*, and for sensitization and intracutaneous irritation and ISO 10993-10:2010 *Biological evaluation of medical devices – Part 10: Tests for in irritation and skin sensitization*.

Reprocessing Validation

The ENTity WiFi 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 ENTity WiFi System 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 *Designing, testing, and labeling reusable medical devices for reprocessing in health care settings: A guide for medical device manufacturers*, AAMI TIR 30:2011/R2016 *A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices*, and ASTM E1837-96 *Standard test method to determine the efficacy of disinfection processes for medical devices (simulated use test)*.

Software

The ENTity ICS Software consists of user interface software that allows the user to enter and access patient data stored in the ENTity WiFi Video Processor, perform still image and streaming video capture during an examination, control some ENTity WiFi Videoscope settings, and to generate reports. Software life cycle processes are compliant with IEC 62304 *Medical Device Software – Software Life Cycle Processes.* Software documentation has been provided in accordance with FDA's 2005 *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*. Cybersecurity risks have been assessed and mitigated according to FDA's 2014 *Guidance for the Content of Premarket Submissions Management of Cybersecurity in Medical Devices.*

Wireless Communication

The ENTity WiFi Videoscope and the ENTity WiFi Video Processor exchange data, including streaming image data, over a 2.4 GHz WLAN 802.11 wireless radio connection. All wireless data is encrypted using WPA2 technology for IEEE 802.11. FDA's 2013 *Guidance for Industry and FDA Staff – Radio Frequency Wireless Technology in Medical* Devices was applied for RF wireless technology design, documentation, and testing. Wireless coexistence testing was conducted using a test plan based on AAMI TIR69 and ANSI C63.27.

Dimensional, Functional, and Performance Testing

The ENTity WiFi System has been tested at the component and system level to ensure that all design specifications were met; testing included endoscope dimensional and optical measurement, endoscope surface temperature measurement, color performance, limiting spatial resolution, modulation transfer function (MTF), distortion, image intensity uniformity, signal to noise, dynamic range, rechargeable battery and battery charger performance verification, camera performance evaluation, videoscope moisture resistance testing, verification of hazards mitigations, and system performance evaluation. Comparative end-to-end (E2E) latency testing demonstrated that the E2E latency of the ENTity WiFi System is comparable to that of the predicate device system when used together with the reference device. The measured E2E latency of both the ENTity WiFi System and the predicate Karl Storz System with the reference NDS Surgical Imaging ZeroWire G2 was greater than 160ms and less than 200ms.

The ENTity WiFi 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 WiFi 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.*

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 WiFi System raises no new questions of safety and effectiveness, and is substantially equivalent to predicate device.