August 11, 2025

ResnENT, LLC
℅ Billi-Jo Pfalzgraf
Regulatory Consultant
MedEdge Consulting
7005 Evergreen Pl
Roswell, Georgia 30076

Re: K241731
Trade/Device Name: Outlook Surgical Versa One System (8900139)
Regulation Number: 21 CFR 874.4760
Regulation Name: Nasopharyngoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOB
Dated: July 29, 2025
Received: July 29, 2025

Dear Billi-Jo Pfalzgraf:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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.

Submission Number *(if known)*

K241731

Device Name

Outlook Surgical Versa One System (8900139)

Indications for Use *(Describe)*

The Outlook Surgical Versa One System is intended for use in examination and visualization in otolaryngology and head and neck 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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Outlook Surgical Versa One System 510(k)

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date: August 8, 2025

1.0 SUBMITTER:
ResnENT, LLC
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1.1 PRIMARY CONTACT PERSON:
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1.2 SECONDARY CONTACT PERSON:
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MedEdge Consulting
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2.0 DEVICE:

Trade Name:	Outlook Surgical Versa One System
Common/Usual Name:	Flexible Nasopharyngoscope System
Classification Name:	Nasopharyngoscope (flexible or rigid) (21 CFR 874.4760)
Regulatory Class:	II
Product Code:	EOB

3.0 PREDICATE DEVICE:
The subject device is equivalent to the following devices:

- K191102 Stryker Precision S 4K Sinuscope

4.0 DEVICE DESCRIPTION:
The Outlook Surgical Versa One System is a video nasopharyngoscopy system that provides illumination and live video stream of a patient's internal anatomy during otolaryngology and head and neck examinations and procedures. The device is composed of an endoscope, a connection cable available in 6ft or 12ft lengths, a wireless enabled display unit, and a wireless HDMI receiver. Users attach accessory instruments to the semi-flexible shaft of the endoscope enabling the user to visualize with the instrument attached.

The device will be used by clinical practitioners in a sterile field in an operating room, healthcare clinic, or medical office. The Outlook Surgical Versa One System is a reusable device initially

supplied as non-sterile to the user and requiring the user to process (i.e., clean and sterilize) the device for initial use, as well as to reprocess the device after each use.

The Versa One Endoscope has a semi-flexible shaft that enables the user to attach instruments. The semi-flexible shaft is rigid near the adapter end and semi-flexible at the distal end to conform the shape of the attached instrument. When an instrument is attached to the scope, the flexible portion becomes rigid and the scope functions as a rigid endoscope. The Versa One endoscope is compatible with Versa One straight and curved sheaths.

The Outlook Surgical Versa One System live stream video can be viewed on the display unit and an off-the-shelf monitor connected to the display unit via an HDMI cable or wirelessly. The off-the shelf monitor is not provided with the device. The device operates off rechargeable battery power.

The Versa One Endoscope uses an integrated LED light source to illuminate glass fiber bundles in the shaft and a CMOS sensor at the distal tip to send the signal to a custom PCB in the endoscope handle that converts the signal to live video.

5.0 INDICATIONS FOR USE:
The Outlook Surgical Versa One System is intended for use in examination and visualization in otolaryngology and head and neck procedures.

6.0 SUBSTANTIAL EQUIVALENCE:
The Outlook Surgical Versa One System is similar to the predicate in several ways. Both devices have the same intended use, indication for use, and the same use environment. Both devices illuminate and provide visualization of the patient's anatomy. The subject and predicate devices perform as rigid endoscopes with the same direction of view and lack of articulation control and internal channel. Both devices are reusable and use similar methods of reprocessing. Performance and safety testing has demonstrated that technical differences raise no new questions of safety and effectiveness. Thus, the subject Outlook Surgical Versa One System is substantially equivalent to the predicate Stryker Precision S 4K Sinuscope.

The table below compares the intended use and technological characteristics of the subject and predicate device.

Feature	Outlook Surgical Versa One System (Subject Device)	Stryker Precision S 4K Sinuscope (Predicate Device)	Similarities and Differences
510(k)	K241731	K191102	
Common Name	Nasopharyngoscope System	Sinuscope	
Classification Name	Nasopharyngoscope (flexible or rigid) and Accessories	Nasopharyngoscope (flexible or rigid) and Accessories	Same
Device Class	Class II	Class II	Same
Regulation	21 CFR 874.4760	21 CFR 874.4760	Same
Product Code	EOB	EOB	Same
Indication for Use	The Outlook Surgical Versa One System is intended for use in examination and	The Precision S 4K Sinuscope is intended for use in otolaryngology and	Similar. Narrower indication for use does not

Feature	Outlook Surgical Versa One System (Subject Device)	Stryker Precision S 4K Sinuscope (Predicate Device)	Similarities and Differences
	visualization in otolaryngology and head and neck procedures.	Head and Neck procedures, including rhinology, and endoscopic plastic and reconstructive surgery.	raise new questions of safety or effectiveness.
Use Environment	Medical facilities	Medical facilities	Same
Principle of Operation	Attach proximal end to provided power source, attach scope shaft to instrument to create rigid scope configuration and insert into nose or mouth	Attach proximal end to light source and camera and insert rigid scope into nose or mouth	Performance testing and User Validation demonstrate this difference does not raise new questions of safety and effectiveness.
Image transmission	CMOS sensor at distal tip transfers images to integrated handheld monitor with video processor to display live stream images.	Rod lenses with camera/monitor connected to sinuscope eyepiece	Optical performance testing demonstrates this difference does not raise new questions of safety and effectiveness.
Wireless video transmission	Yes. Optional wireless data transfer between handheld monitor and wireless receiver.	No	Safety testing in accordance with IEC 60601-1, IEC 60601-2-18, IEC 63195-1, and ANSI/IEEE C95.1 demonstrates this difference does not raise new questions of safety and effectiveness.
Internal working channel	No	No	Same
Shaft type	Rigid when in use (attached to instrument)	Rigid shaft	Same
Required Accessories	Sheath required for use	No	User Validation and Performance testing demonstrate this difference does not raise new questions of safety and effectiveness.
Shaft Outer Diameter	3.0mm, 3.8mm	3.1mm, 4.0mm	Performance and User Validation demonstrates this difference does not raise new questions of safety or effectiveness.
Shaft Working Length	102mm - 105mm	125mm - 180mm	Performance and User Validation testing demonstrate this difference does not raise new questions of safety and effectiveness.
Articulation Control	No	No	Same

Feature	Outlook Surgical Versa One System (Subject Device)	Stryker Precision S 4K Sinuscope (Predicate Device)	Similarities and Differences
Scope Direction of View	0º	0º - 70º	Same
Scope Field of View	120º	80º - 105º	User Validation and Performance testing demonstrate this difference does not raise new questions of safety and effectiveness.
Scope Power Source	Rechargeable Li-ion battery or AC power from control box through cable connected to scope.	Light source powered externally and coupled to scope.	Electrical safety testing in accordance with IEC 60601-1 and 60601-2-18 demonstrate this difference does not raise new questions of safety and effectiveness.
Illumination Output	Illumination fibers; commercially available source	Illumination fibers, commercially available source	Same
Light Source	Integrated LED	External light source coupled to scope	Electrical safety testing in accordance with IEC 60601-1 and 60601-2-18 and Photobiological testing in accordance with IEC 62471 demonstrates this difference does not raise new questions of safety and effectiveness.
Key Patient-Contacting Materials	304 stainless steel, glass, borosilicate, crosslinked polyvinylidene fluoride, epoxy	Stainless Steel, optical glass, glass fibers	Biocompatibility testing in accordance with ISO 10993 and performance testing demonstrates this difference does not raise new questions of safety and effectiveness.
Single Use or Reusable	Reusable – scope Single Use – accessories	Reusable	Sterilization validation in accordance with ISO 11135 and ISO 10993-7 demonstrates this difference does not raise new questions of safety and effectiveness.
Scope Reprocessing	Manual cleaning followed by APS STERRAD Sterilization	Manual and automated cleaning, manual and automated disinfection, autoclave, Steris VPRO, and APS STERRAD sterilization	Similar

7.0 PERFORMANCE DATA:

The table below lists all of the testing that has been performed on the Outlook Surgical Versa One System.

Test	Test Method Summary	Results
Performance Testing: Simulated Use/Cycling	The Versa One endoscope was tested to show the device performs as intended through multiple simulated use procedures and repeated instrument attachment/detachment cycles.	Passed. All acceptance criteria were met. The simulated use testing is relevant to determining substantial equivalent because it demonstrates the subject device performs as intended as a rigid scope when attached to an instrument. The cycling testing demonstrates that the subject device performs as expected and can be used safely throughout its minimum expected use life.
User Validation	FDA Guidance document "Applying Human Factors and Usability Engineering to Medical Devices", IEC 62366-1. Multiple users were presented with all device components and followed the IFU to set up and use the system using an anatomical model and to confirm results in a cadaver model.	Passed. All users were able to choose the appropriate attachment for a procedure, attach the instrument to the scope, and perform the simulated procedure with the device. This test is relevant to determining substantial equivalence because it demonstrates users can use the device as intended in the expected use environment.
Performance Testing: Optical Performance	Testing was conducted according to ISO 8600-X, ISO 12233, and ISO 15739 for optical performance. Image capture and analysis software was used to evaluate signal to noise ratio and dynamic range, image quality (geometric distortion, MTF, and FOV), image intensity uniformity, and color accuracy. Endoscope image latency was also measured.	Passed. All devices met performance criteria. This testing is relevant in determining substantial equivalence because the subject device and predicate are both intended to illuminate and visualize patient anatomy.
Performance Testing: Simulated Use	The Outlook Surgical Versa One System was tested for automatic exposure control, wireless link distance, Display power up, battery charge, battery status indicator, image rotation, and HDMI port activity. Versa One Endoscopes were evaluated for shaft durability and bend radius using an automated process.	Passed. All systems met performance criteria. This testing is relevant in determining substantial equivalence because it demonstrates the subject device reliably performs as intended. The reliability of the wireless link distance supports substantial equivalence of the subject device to the predicate device with wireless transmission of images.

Performance Testing: Electrical Requirements (non 60601-1)	The Versa One Display and Wireless HD Receiver were inspected for electrical requirements not included in IEC 60601-1 or IEC 60601-2-18 testing. Device charger and Display MOPP, isolation barriers, and HDMI connectors were inspected.	Passed. All devices met criteria. This test is relevant in determining substantial equivalence because is demonstrates the subject device safely and reliably performs as intended.
Performance Testing: Dimension, Material, Environmental	Versa One Endoscopes were tested for patient-contacting surface temperature, water splash testing, ambient temperature testing, dimensional and material requirements, cable force measurement and leak testing of the distal end.	Passed. This is relevant to determining substantial equivalence because the subject device and predicate used to illuminate and visualize patient anatomy and have the same use environment.
Electrical Safety, electromagnetic compatibility (EMC), and RF Safety	Testing was conducted in compliance with the IEC 60601-1 and IEC 60601-2-18 for electrical safety, IEC 60601-1-2 for EMC, IEC 63195-1, and ANSI/IEEE C95.1-1 for RF Safety	Passed. This test is relevant in determining substantial equivalence because the it demonstrates the electrical safety, electromagnetic compatibility, and RF safety of the subject device.
Photobiological Safety	Testing was conducted in accordance with IEC 62471 for photobiological safety.	Passed. This test is relevant in determining substantial equivalence because it demonstrates the photobiological safety of the subject device.
Cleaning Validation	FDA Guidance document Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, AAMI TIR12 and AAMI ST98.	Passed. This test is relevant in determining substantial equivalence because the subject device and predicate device are both cleaned manually.
Biocompatibility Testing	FDA Guidance, "Use of International Standard ISO 10993-1, 'Biological evaluation and testing within a risk management Process' and 10993-1: Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process. (ISO 10993-5, ISO 10993-10, ISO 10993-23)	Passed. Non-cytotoxic, non-sensitizing, non-irritating, non-systemically toxic, and non-pyrogenic. This test is relevant in determining substantial equivalence because it demonstrates any material differences between the subject device and the predicate do not raise new questions of safety.
Sterilization Validation	For scope: ISO 22441:2022 Sterilization of health care products, low temperature vaporized hydrogen peroxide – Requirements for the development, validation and routine control of sterilization process for medical devices. The Overkill test method was used. For sheaths: ISO 11135:2014 Sterilization of health care products –	Passed. This test is relevant in determining substantial equivalence because the subject device and predicate device are both reprocessed with APS STERRAD sterilization. Sterilization validation for the sheaths is relevant in determining substantial equivalence because it demonstrates the sterile, single-use accessories do not raise

	Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices.	new questions of safety or effectiveness.

8.0 CONCLUSION:

The results of the performance testing described above demonstrate that the Outlook Surgical Versa One System is as safe and effective as the predicate device and supports a determination of substantial equivalence.