July 1, 2022

Medimaging Integrated Solution Inc. (MiiS)
Jung-Yi Yen
Regulatory Affairs
3F., No.24-2, Industry E. Rd. IV, Hsinchu Science Park
Hsinchu, Taiwan 30077
Taiwan

Re: K214050
Trade/Device Name: ENT Nasopharyngoscope and Accessories
Regulation Number: 21 CFR 874.4760
Regulation Name: Nasopharyngoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOB
Dated: May 26, 2022
Received: June 3, 2022

Dear Jung-Yi Yen:

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 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K214050

Device Name
ENT Nasopharyngoscope and Accessories

Indications for Use *(Describe)*
The ENT Nasopharyngoscope EES 100 is a sterile, single-use, and flexible device intended to be operated with its compatible display (EVS 100) for endoscopic procedures within nasal lumens and upper airway anatomy.
The Video Box EVS 100 is intended to provide visualization via the connected tablet.
The Nasopharyngoscope is intended for use in a hospital environment. It is designed for adult use.

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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Medimaging Integrated Solution Inc.

510(k) Summary

Prepared:	July 1st , 2022
Submitter/Owner's Name/ Address	Medimaging Integrated Solution Inc. (MiiS) 3F., No.24-2, Industry E. Rd. IV, Hsinchu Science Park, Hsinchu, Taiwan 30077, R.O.C.
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Device Identification:

Trade/Device Name: ENT Nasopharyngoscope and Accessories.
Common Name: Nasopharyngoscope
Regulation Number: 21 CFR 874.4760
Regulation Name: Nasopharyngoscope (Flexible Or Rigid)
Regulatory Class: Class II
Product Code: EOB

Predicate Device:

K191080
Trade/Device Name: Ambu aScope 4 RhinoLaryngo Slim
Regulation Number: 21 CFR 874.4760
Regulation Name: Nasopharyngoscope (Flexible Or Rigid)
Regulatory Class: Class II
Product Code: EOB

Description of Device:

ENT Nasopharyngoscope and Accessories contain nasopharyngoscope (model name: EES 100) and image transfer system (Video Box, model name: EVS 100A). EES 100 is a single-use, flexible, sterile nasopharyngoscope. The illumination LED locate at the tip of the distal end. There is a bending section near the region of distal end, which manipulated by the control lever on the handle part, can provide visions with more than one direction for the users. The signal captured was then transmitted to the cable-connected Video Box (EVS 100A).

EVS 100A is attached on a tablet. The live imaging or snapshot will present directly on the tablet.

The function of Nasopharyngoscope is to provide live imaging of the nasal tissue, including tissue appearance recording, snapshot, vertical flip and horizontal flip. The device does not provide any instruction for diagnosis nor treatment. Table 1 below includes a summary of the technical information used in the substantial equivalence comparison.

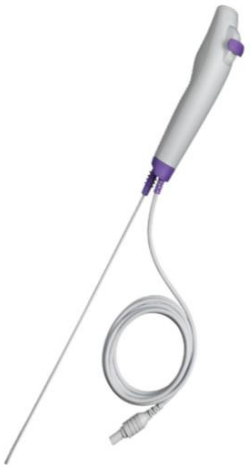
Indications for Use (IFU):

The ENT Nasopharyngoscope EES 100 is a sterile, single-use, and flexible device intended to be operated with its compatible display (EVS 100) for endoscopic procedures within nasal lumens and upper airway anatomy.
The Video Box EVS 100 is intended to provide visualization via the connected tablet.
The nasopharyngoscope is intended for use in a hospital environment. It is designed for use in adults.

Substantial Equivalence Summary

Below is a summary table comparing the IFUs and key technological characteristics between the subject and the predicate devices.

Device	K214050	K191080
Model name	Nasopharyngoscope: EES 100 Video Box: EVS 100A	Ambu aScope 4 RhinoLaryngo Slim
Product code & Classification	21 CFR 874.4760, EOB Class II	21 CFR 874.4760, EOB Class II
Intended use	The ENT Nasopharyngoscope EES 100 is a sterile, flexible, single-use device intended to be used with compatible display. This device is indicated for endoscopic diagnosis procedures within the nasal lumen and upper airway anatomy. The Video Box EVS 100 is intended to provide visualization via a monitor. The nasopharyngoscope is intended for use in a hospital environment. It is designed for use in adults.	The endoscope is a sterile, single-use, flexible endoscope intended for endoscopic procedures and examination within the nasal lumens and upper airway anatomy. The endoscope is intended to provide visualization via Ambu displaying unit. The endoscope is intended for use in a hospital environment. It is designed for use in adults.
Lens Specification	FOV: 90° DOV: 0° DOF: 7-50 mm	FOV: 85° DOV: 0° DOF: 6-50 mm

Mechanical Specification	Bending angle: 130° (up and down) Working length: 300 mm Outer diameter: 3.6 mm	Bending angle: 130° (up and down) Working length: 300 mm Outer diameter: 3.5 mm
EMC	IEC 60601-1-2	IEC 60601-1-2
Safety	IEC 60601-1 IEC 60601-2-18	IEC 60601-1 IEC 60601-2-18
Bench test	ISO 8600-1 ISO 8600-3 ISO 8600-4	ISO 8600-1 ISO 8600-3 ISO 8600-4
Sterilization	EO Sterilization	EO Sterilization
LED Light source	At distal tip	At distal tip
Appearance		

Substantial Equivalence Discussion

Similarities:

- ENT Nasopharyngoscope and Accessories and the predicate device, Ambu aScope 4 RhinoLaryngo Slim (K191080), have the same intended use and similar specifications in field of view, direction of view, depth of field, bending angle, working length, outer diameter, sterilization method, light source location and appearance.

Differences:

- The main differences lie in the optical specification (including field of view and depth of field) and the outer diameter of the insertion tube. For all these features, the differences are not more than 10%, and the image performance and the usability of the device are both validated in usability testing, optical performance and color performance testing. Thus, it is considered that there is no significance difference occurs between ENT Nasopharyngoscope and Accessories with its predicate devices.

Nonclinical Tests

The following tests have been performed in support of the substantial equivalence determination:

- IEC/EN 60601-1:2005/2006+A1:2012/2013 for electrical safety.
- IEC/EN 60601-1-2:2014/2015 for electromagnetic compatibility.
- ISO 11135:2014 for sterilization validation
- ISO 11607-1:2019 for package integrity test.
- ISO 10993-7:2008 for EO/ECH Residue
- ASTM D4169-16 for transportation test.
- ASTM F1980-16 for aging test.
- ISO 11737-1:2019 for sterility test.
- ISO 14971:2019, EN ISO 14971:2019 and MDR 2017/745 for risk management.
- IEC 62471:2006 for light hazards.
- ISO10993-5:2009 and ISO10993-10:2010 standards for biocompatibility. The patient contacting parts is the applied part of the ENT Nasopharyngoscope EES 100.

Clinical Tests

No clinical studies were performed.

Optical Radiation Safety Assessment

The ENT Nasopharyngoscope EES 100 was tested according to ISO 62471:2006 to determine acceptable light safety limits for both the illumination. The test results demonstrate the ENT Nasopharyngoscope EES 100 meets the requirements of the standard.

Conclusion

Substantial equivalence comparison and bench performance tests support the conclusion of substantial equivalence of ENT Nasopharyngoscope and Accessories to the predicate devices Ambu aScope 4 RhinoLaryngo Slim (K191080).