April 1, 2022

Sonoscape Medical Corp.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O.box 120-119
Shanghai, 200120
CHINA

Re: K211882
Trade/Device Name: HD-550 Video Endoscope System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: NWB, FDF, FDS
Dated: March 25, 2022
Received: March 29, 2022

Dear Diana Hong:

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,

Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology 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)*
K211882

Device Name
HD-550 Video Endoscope System

Indications for Use *(Describe)*

HD-550 Video Endoscope System
The HD-550 video endoscope system, which includes a video gastroscope /video colonoscope, image processor, light source, monitor, accessories and other peripheral devices, is intended for endoscopic examination, diagnosis and treatment of the upper and lower gastrointestinal tract.

EG-550 Series Video Gastroscope
The EG-550 Series Video Gastroscope has been designed to be used with the image processor, light source, monitor and other peripheral devices for endoscopic observation, diagnosis and treatment of the upper digestive tract (including the esophagus, stomach and duodenum).

EC-550 Series Video Colonoscope
The EC-550 Series Video Colonoscope has been designed to be used with the image processor, light source, monitor and other peripheral devices for endoscopic observation, diagnosis and treatment of the lower digestive tract (including the anus, rectum, colon and ileocecal segment).

HD-550 Series Image Processor
The HD-550 Series Image Processor has been designed to be used with the endoscope, light source, monitor and other peripheral devices for endoscopic observation, diagnosis, treatment, and video recording.

VLS-55 Series Light Source
The VLS-55 Series Light Source has been designed to be used with the endoscope, image processor and other peripheral devices for endoscopic observation, diagnosis and treatment.

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

This 510(k) Summary is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K211882

1. Date of Preparation: 03/28/2022

2. Sponsor Identification

SONOSCAPE MEDICAL CORP.
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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
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4. Identification of Proposed Device

Trade Name: HD-550 Video Endoscope System
Common Name: Endoscopic Video Imaging System
Primary Components and Component Models:

HD-550 Video Endoscope System	EG-550 Series Video Gastroscope	EG-550, EG-550L
	EC-550 Series Video Colonoscope	EC-550, EC-550T, EC-550L, EC-550L/T
	HD-550 Series Image Processor	HD-550Exp, HD-550, HD-550Pro, HD-550S, HD-510, HD-500Plus
	VLS-55 Series Light Source	VLS-55Q, VLS-55T, VLS-51T, VLS-51D

Regulatory Information
Classification Name: Endoscope and accessories
Classification: II
Product Code: NWB, FDF and FDS
Regulation Number: 21 CFR 876.1500
Review Panel: Gastroenterology/Urology

Indications for Use:
HD-550 Video Endoscope System
The HD-550 video endoscope system, which includes a video gastroscope /video colonoscope, image processor, light source, monitor, accessories and other peripheral devices, is intended for endoscopic examination, diagnosis and treatment of the upper and lower gastrointestinal tract.

EG-550 Series Video Gastroscope
The EG-550 Series Video Gastroscope has been designed to be used with the image processor, light source, monitor and other peripheral devices for endoscopic observation, diagnosis and treatment of the upper digestive tract (including the esophagus, stomach and duodenum).

EC-550 Series Video Colonoscope
The EC-550 Series Video Colonoscope has been designed to be used with the image processor, light source, monitor and other peripheral devices for endoscopic observation, diagnosis and treatment of the lower digestive tract (including the anus, rectum, colon and ileocecal segment).

HD-550 Series Image Processor
The HD-550 Series Image Processor has been designed to be used with the endoscope, light source, monitor and other peripheral devices for endoscopic observation, diagnosis, treatment, and video recording.

VLS-55 Series Light Source
The VLS-55 Series Light Source has been designed to be used with the endoscope, image processor and other peripheral devices for endoscopic observation, diagnosis and treatment.

5. Device Description

The proposed device, HD-550 Video Endoscope System, which includes a video gastroscope /video colonoscope, image processor, light source, monitor, accessories and other peripheral devices.

HD-550 Video Endoscope System can be offered in several configurations with the options of different models of primary components

The EG-550 Series Video Gastroscope/ EC-550 Series Video Colonoscope is the hand-held, direct-viewing flexible endoscope used for endoscopy and endoscopic surgery within the upper and lower gastrointestinal tract.

The HD-550 Series Image Processor is a video processing system which is designed to be used with endoscopes, light source, monitor of the proposed system. Apart from the image processing functions, it also provides power supply for the endoscopes.

The VLS-55 Series Light Source provides illumination for endoscopic diagnosis, treatment and video observation.

6. Identification of Predicate Device

510(k) Number: K173921
Product Name: HD-500 Video Endoscope System.
Primary Components and Component Models:

EG-500 Series Video Gastroscope	EG-500, EG-500L
EC-500 Series Video Colonoscope	EC-500, EC-500T, EC-500L, EC-500L/T
HD-500 Series Image Processor	HD-500, HD-500S, HD-330Plus
HDL-500 Series Light Source	HDL-500E, HDL-500X

7. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- IEC 60601-1-2005+CORR.1:2006+CORR.2:2007+A1:2012, Medical Electrical Equipment- Part 1: General requirements for basic safety and essential performance, including the US National Differences
- IEC 60601-1-2:2007, Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic compatibility- Requirements and tests
- IEC 60601-2-18:2009, Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
- ISO 8600-1:2015 Endoscopes--Medical endoscopes and endotherapy devices - part 1: General requirements
- ISO 8600-7:2012 Endoscopes --Medical endoscopes and endotherapy devices - part 7: Basic requirements for medical endoscopes of water-resistant type
- ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization

Optical performance testing

The following testing was conducted to evaluate the optical performance characteristics for each endoscopic system mode.

- Photobiological safety
- Color Reproduction (test results comparison between the proposed device and predicate device)
- Resolution (test results comparison between the proposed device and predicate device)
- Depth of field (test results comparison between the proposed device and predicate device)
- Optical magnification and distortion (test results comparison between the proposed device and predicate device)
- Image intensity uniformity (test results comparison between the proposed device and predicate device)

Physical/functional performance testing

The endoscope performance test was conducted to evaluate the ability of proposed endoscope to maintain the maximum angulation/deflection when in use, the physical/functional performance of the proposed device, including a) Appearance visual inspection and handle strength inspection, b) Image function visual inspection, c) Sealing performance, and d) Maximum bending angle measurement and body model testing.

Imaging performance testing

The imaging performance testing was conducted to demonstrate that the imaging quality of the proposed device is still in a better condition when the device is over its lifetime of clinical use. The degradations of imaging performance are very little which will not affect the normal use of the endoscope.

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Substantially Equivalent (SE) Comparison

The whole system and components of the proposed device is basically identical to its predicate device in indication for use, and similar in specification. Comparisons between the proposed device and predicate device are shown in Table 1 to Table 6.

Table 1 General Comparison

ITEM	Proposed Device	Predicate Device K173921
Product Code	NWB, FDF and FDS	NWB, FDF and FDS
Regulation Number	21 CFR 876.1500	21 CFR 876.1500
Class	II	II
Indications for Use	HD-550 Video Endoscope System The HD-550 video endoscope system, which includes a video gastroscope /video colonoscope, image processor, light source, monitor, accessories and other peripheral devices, is intended for endoscopic examination, diagnosis and treatment of the upper and lower gastrointestinal tract.	HD-500 Video Endoscope System The HD-500 Video Endoscope System, which includes a video gastroscope /video colonoscope, image processor, light source, monitor, accessories and other peripheral devices, is intended for endoscopies examination, diagnosis and treatment of the disease of the upper and lower gastrointestinal tract.
	VLS-55 Series Light Source, The VLS-55 Series Light Source has been designed to be used with the endoscope, image processor and other peripheral devices for endoscopic observation, diagnosis and treatment.	HDL-500 Series Light Source, HDL-500E, HDL-500X The HDL-500 Series Light Source has been designed to be used with the endoscope, image processor and other peripheral devices for endoscopic observation, diagnosis and treatment.
	HD-550 Series Image Processor, The HD-550 Series Image Processor has been designed to be used with the endoscope, light source, monitor and other peripheral devices for endoscopic observation, diagnosis, treatment, and	HD-500 Series Image Processor, HD-500, HD-500S, HD-330Plus The HD-500 Series Image Processor has been designed to be used with the endoscope, light source, monitor and other peripheral devices for endoscopic

	video recording.	observation, diagnosis, treatment, and video recording.
	EG-550 Series Video Gastroscope The EG-550 Series Video Gastroscope has been designed to be used with the image processor, light source, monitor and other peripheral devices for endoscopic observation, diagnosis and treatment of the upper digestive tract (including the esophagus, stomach and duodenum).	EG-500 Series Video Gastroscope, EG-500, EG-500L The EG-500 Series Video Gastroscope has been designed to be used with the image processor, light source, monitor and other peripheral devices for endoscopic observation, diagnosis and treatment of the upper digestive tract (including the esophagus, stomach and duodenum).
	EC-550 Series Video Colonoscope The EC-550 Series Video Colonoscope has been designed to be used with the image processor, light source, monitor and other peripheral devices for endoscopic observation, diagnosis and treatment of the lower digestive tract (including the anus, rectum, colon and ileocecal segment).	EC-500 Series Video Colonoscope, EC-500, EC-500T, EC-500L, EC-500L/T The EC-500 Series Video Colonoscope has been designed to be used with the image processor, light source, monitor and other peripheral devices for endoscopic observation, diagnosis and treatment of the lower digestive tract (including the anus, rectum, colon and ileocecal segment)
Configuration (primary components)	Light Source	Light Source
	Image processor	Image processor
	Video Gastroscope	Video Gastroscope
	Video Colonoscope	Video Colonoscope
	Accessories and peripheral devices	Accessories and peripheral devices

Table 2 Specifications Comparison of Image Processor

ITEM		Proposed Device						Predicate Device K173921
Model		HD-550Exp	HD-550	HD-550Pro	HD-550S	HD-510	HD-500Plus	HD-500
Power supply		100-240V AC, 50/60Hz						100-240V AC, 50/60Hz
Over-current protection		Fuse type						Fuse type
Size		370(W)×124(H)×500(D)mm		370(W)×124(H)×500(D)mm		370(W)×124(H)×500(D)mm		370(W)×124(H)×455(D)mm
Weight		11.1 Kg		11.1 Kg		11.1 Kg		9.5 Kg
compatible endoscope		Videoscope						Videoscope
Observation	Video signal output	DVI (high definition) VGA (high definition) SDI (high definition) CVBS (standard definition) S-Video (standard definition)						DVI VGA SDI VBS Y/C
	Auto white balance	Automatically adjusted using the white balance switch. At the time of connection with the scope in which the scope ID is provide, compensation is performed automatically						Automatically adjusted using the white balance switch. At the time of connection with the scope in which the scope ID is provide, compensation is performed automatically
	Standard color char output	Color bar image						Color bar image
	color tone	Red: ±15 steps, Blue: ±15 steps, chroma: ±15 steps						R:±8 steps B:±8 steps

	adjustment		chroma:±8 steps
	automatic gain control	Provided	Provided
	Image enhancement	Edge enhancement Structure enhancement: Contrast enhancement Color enhancement:	Edge enhancement Structure enhancement: Contrast enhancement Color enhancement:
	IRIS mode selection	Peak/AVE/Auto photometry mode	Peak/AVE/Auto photometry mode
	Zoom	1.0 - 4.0	×1.4 /×1.6/×1.8
	Imaging modes	White light (WL) imaging mode, Enhanced white light (EWL) imaging mode, Spectral focused (SFI mode) imaging mode and Intelligent staining technology mode (VIST mode)[NOTE]	WL imaging mode, VIST observation mode
Foot switch connector		Provided	Provided
record to memory card		Provided	Provided

NOTE:
The prospective clinical value of the enhanced imaging modes has not been demonstrated, and no clinical claims are made.

Table 3 Specifications Comparison of Video Gastroscope

ITEM	Proposed device		Predicate device		Remark
Model	EG-550	EG-550L	EG-500	EG-500L	/
Field of view	140°	140°	140°	140°	SE
Depth of focus	3-100mm	3-100mm	3-100mm	3-100mm	SE
Front view	0°	0°	0°	0°	SE
Sensor type	color CMOS	color CMOS	color CMOS	color CMOS	SE
Distal end outer diameter	9.3mm	9.8mm	9.3mm	9.8mm	SE
Insertion section outer diameter	9.3mm	9.8mm	9.3mm	9.8mm	SE
Bend angle	UP:210° DOWN:90° RIGHT:100° LEFT:100°	UP:210° DOWN:90° RIGHT:100° LEFT:100°	UP:210° DOWN:90° RIGHT:100° LEFT:100°	UP:210° DOWN:90° RIGHT:100° LEFT:100°	SE
Insertion section length	1050mm	1050mm	1050mm	1050mm	SE
Total length	1400mm	1400mm	1400mm	1400mm	SE
Biopsy channel inner diameter	2.8mm	3.2mm	2.8mm	3.2mm	SE

Table 4 Specifications Comparison of Video Colonoscope

ITEM	Proposed device				Predicate device	Remark
Model	EC-550	EC-550T	EC-550L	EC-550L/T	EC-500	/
Field of view	140°	140°	140°	140°	140°	SE
Depth of focus	3-100mm	3-100mm	3-100mm	3-100mm	3-100mm	SE
Front view	0°	0°	0°	0°	0°	SE
Sensor type	color CMOS	color CMOS	color CMOS	color CMOS	color CMOS	SE
Distal end outer diameter	12mm	12mm	12.9mm	12.9mm	12mm	SE analysis 6
Insert section outer diameter	12.5mm	12.5mm	12.9mm	12.9mm	12.5mm	SE analysis 6
Bend angle	UP:180° DOWN:180° RIGHT:160° LEFT:160°"	UP:180° DOWN:180° RIGHT:160° LEFT:160°	UP:180° DOWN:180° RIGHT:160° LEFT:160°	UP:180° DOWN:180° RIGHT:160° LEFT:160°	UP:180° DOWN:180° RIGHT:160° LEFT:160°	SE
Insertion section length	1350mm	1700mm	1350mm	1700mm	1350mm	SE analysis 7
Total length	1700mm	2050mm	1700mm	2050mm	1700mm	SE analysis 7
Biopsy channel inner diameter	≥ 3.8mm	≥ 3.8mm	≥ 4.2mm	≥ 4.2mm	3.8mm	SE analysis 6

Table 5 Specifications Comparison of Light Source

ITEM	VLS-55 Series Light Source	HDL-500E Light Source	Remark
Power supply	AC 100-240V 50Hz/60Hz	AC 100-240V 50Hz/60Hz	SE
Over-current protection	Fuse type	Fuse type	SE
Input current	300VA	160VA	SE Analysis 8
Examination lamp	50W LED	50W LED	SE
Average lamp life	50000 hours	50000 hours	SE
Emergency lamp	14W LED	14W LED	SE
Average emergency lamp life	50000 hours	50000 hours	SE
Brightness control	Automatic and manual	Automatic and manual	SE
Automatic exposure	19 steps	19 steps	SE
System connector	Provided	Provided	SE
Foot switch connector	Provided	Provided	SE
CV connector	Provided	Provided	SE

Table 6 Safety Comparison

ITEM	Proposed Device HD-550 Video Endoscope System		Predicate Device K173921 HD-500 Video Endoscope System		Remark
Electrical Safety	Comply with IEC 60601-1		Comply with IEC 60601-1		SE
EMC	Comply with IEC 60601-1-2		Comply with IEC 60601-1-2		SE
Particular requirements	Comply with IEC 60601-2-18		Comply with IEC 60601-2-18		SE
Product Performance	Comply with ISO 8600-1 and ISO 8600-7		Comply with ISO 8600-1 and ISO 8600-7		SE
Patient-contact component and material	Insertion section	PU, fluoroelastomer	Insertion section	PU, fluoroelastomer	SE
	Distal end	PEEK, Sapphire crystal SUS 304	Distal end	PEEK, Sapphire crystal SUS 304	
	Adhesive	Epoxy resin	Adhesive	Epoxy resin	
Biocompatibility	Cytotoxicity, ISO 10993-5		Cytotoxicity, ISO 10993-5		SE
	Sensitization, ISO 10993-10		Sensitization, ISO 10993-10		
	Irritation, ISO 10993-10		Irritation, ISO 10993-10		

10. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis in section 9 and the side-by-side optical performance tests, the proposed device and the predicate device have the same intended use, comparable product specification and optical performance. Therefore, the proposed device is determined to be Substantially Equivalent (SE) to the predicate device.