March 8, 2024

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

Re: K231813
Trade/Device Name: Ultrasonic Gastrovideoscope
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: ODG, ITX
Dated: February 7, 2024
Received: February 7, 2024

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 (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.

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,

Shanil P. Haugen -S

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)*
K231813

Device Name
Ultrasonic gastrovideoscope

Indications for Use *(Describe)*
The ultrasonic gastrovideoscope (hereinafter called endoscope) is intended to provide endoscopic images for the examination and diagnosis of the upper gastrointestinal tract and to perform the ultrasound examination and diagnosis of the upper gastrointestinal sub-mucosa and the surrounding organs.

The endoscope should be used in the medical institution. The operator of the endoscope should be a physician or a medical staff supervised by a physician, both of whom have received sufficient training in clinical endoscopy technology.

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 Title 21, CFR Section 807.92.

The assigned 510(k) Number: K231813

1. Date of Preparation: 03/06/2024

2. Sponsor Identification

SONOSCAPE MEDICAL CORP.
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3. Designated Submission Correspondent

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Ms. Jing Cheng (Alternative Contact Person)

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4. Identification of Subject Device

Device Trade Name: Ultrasonic Gastrovideoscope (EG-UR5)
Common Name: Endoscope and accessories

Regulatory Information
Classification Name: Endoscopic Ultrasound System, Gastroenterology-Urology
Product Class: II
Product Code: ODG
Regulation Number: 21 CFR 876.1500

Indication for Use:
The ultrasonic gastrovideoscope (hereinafter called endoscope) is intended to provide endoscopic images for the examination and diagnosis of the upper gastrointestinal tract and to perform the ultrasound examination and diagnosis of the upper gastrointestinal sub-mucosa and the surrounding organs.
The endoscope should be used in the medical institution. The operator of the endoscope should be a physician or a medical staff supervised by a physician, both of whom have received sufficient training in clinical endoscopy technology.

Device Description:
The subject device, Ultrasonic Gastrovideoscope, is consisting of insertion section, control section and connector section. The insertion section is consisting of a distal end, a bending section and an insertion tube. This Ultrasonic Gastrovideoscope is intended to use in conjunction with Endoscopic Image Processor (HD-550Exp, HD-550, HD-550Pro, HD-550S, HD-510 and HD-500Plus), light source (VLS-55Q, VLS-55T, VLS-51D and VLS-51T), ultrasound system (P60 Exp, P60, P60 Pro, P60 CV, P60S and P60 VO) and monitor to provide endoscopic images for the examination and diagnosis of the upper gastrointestinal tract and to perform the ultrasound examination and diagnosis of the upper gastrointestinal sub-mucosa and the surrounding organs.

The Ultrasonic Gastrovideoscope is a reusable device. The Ultrasonic Gastrovideoscope has only one model EG-UR5.

The prospective clinical value of the enhanced imaging modes (EWL, SFI, and VIST) has not been demonstrated, and no clinical claims are made.

5. Identification of Predicate Device

510(k) Number: K130206
Device Name: PENTAX EG-3670URK Ultrasound Video Gastroscope (Radial Array Type) + HI VISION PREIRUS

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the subject device met all design specifications as was Substantially Equivalent (SE) to the predicate device.

Biocompatibility: Cytotoxicity, Skin Sensitization and Oral Mucosal Irritation

Performance Testing- Optical performance characteristics
The optical performance test includes color reproduction, depth of field, intensity uniformity, Optical Magnification and Distortion, resolution and Dynamic Range. The test results demonstrate that the subject device and predicate device have the same or similar optical performance.

Performance Testing - Ultrasonic Performance Contrast Test
Ultrasonic performance contrast test has been conducted on the subject device and predicate device. The test results demonstrate that the performance indexes of ultrasonic quantization imaging are similar. There was no clinically significant difference in the safety and clinical performance of the subject device and predicate device.

Performance Testing - Irrigation Performance Test
Irrigation performance test (including the Air/Water-feeding and Suction Performance) has been conducted on the subject device and predicate device. The test results demonstrate that the subject device and predicate device have the similar irrigation performance.

Performance Testing -Backflow Prevention Test
Backflow Prevention Test has been conducted on the subject device, the tested per FDA guidance, Mitigating the risk of Cross-Contamination from valves and Accessories Used for irrigation through Flexible Gastrointestinal Endoscopes, Document issued on November 29, 2016. The test results demonstrate that the air/water valve of EG-UR5 could effectively prevent the contaminated liquid backflow to the proximal irrigation system, so the prevention backflow function of the EG-UR5 Ultrasonic Gastrovideoscope is effective and reliable.

Performance Testing - Performance stability
A product performance testing was conducted to evaluate the stability of the subject device when in use. This testing includes two parts, one part is the simulated fatigue testing on the subject device, the other part is used to evaluate the product performance after simulated fatigue testing. Based on the test results, the components mechanically fatigue caused by long-period using will not lead to the decrease of endoscope performance during the clinical use; the endoscope appearance, handle strength, image function, sealing and bending angle still meet the clinical requirements.

The quality of an imaging device can change over time when it is in clinical use due to changes in the components. Imaging Performance Attenuation Test Report was conducted to ensure that degradations in imaging performance is detected before it results in reductions in image quality that lead to misdiagnosis. Image performances include Noisy Point, Color Reducibility, Resolution and Bad Point. The four performance testing was separately conducted on the new devices and the accelerated aging devices in one test report

On the whole, the image performance of system still is 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.

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Summary of Technological Characteristics

Table 1. General Comparison

ITEM	Subject Device	Predicate Device K130206	Remark
Product name	Ultrasonic Gastrovideoscope EG-UR5	PENTAX EG-3670URK Ultrasound Video Gastroscope (Radial Array Type)	/
Regulation No.	21 CFR 876.1500	21 CFR 876.1500	Same
Product code	ODG	ODG and ITX	Same
Class	Class II	Class II	Same
Indication for Use	The ultrasonic gastrovideoscope (hereinafter called endoscope) is intended to provide endoscopic images for the examination and diagnosis of the upper gastrointestinal tract and to perform the ultrasound examination and diagnosis of the upper gastrointestinal sub-mucosa and the surrounding organs. The endoscope should be used in the medical	The EG-3670URK, Ultrasound Video Gastroscope, is intended to provide optical visualization of, ultrasonic visualization of, and therapeutic access to, the Upper Gastrointestinal Track including but not restricted to the organs, tissues, and subsystems: Esophagus, Stomach, Duodenum, Small Bowel, and underlying areas. The instrument is introduced per orally when indications consistent with the requirement	Similar

	institution. The operator of the endoscope should be a physician or a medical staff supervised by a physician, both of whom have received sufficient training in clinical endoscopy technology.	for procedure are observed in adult and pediatric patient populations.	
Configuration	Ultrasonic gastrovideoscope including a radial array type ultrasound transducer	Ultrasonic gastrovideoscope including a radial array type ultrasound transducer	Same
Use environment	Medical institution	Medical institution	Same
Principles of Operation	The endoscope has a long, thin, flexible tube to enter the patient's body and capture the video and ultrasonic image of inside of the patient's body.	The endoscope has a long, thin, flexible tube to enter the patient's body and capture the video and ultrasonic image of inside of the patient's body.	Same
Single use/ Reuse	Reuse	Reuse	Same
Sterile	No	No	Same
Prescription Use/OTC	Prescription Use	Prescription Use	Same

Indication for Use Comparison

The subject device and predicate device are all used to provide endoscopic images of the upper gastrointestinal tract of examination and diagnosis, and to perform the ultrasound exam and diagnosis of the upper gastrointestinal sub-mucosa and the surrounding organs. A difference between the subject device and predicate device is the target population. The subject device is only intended for use in adults; this information has been specified in the user manual.

The difference on the indication for use statement does not raise new problem on the safety and effectiveness of the subject device.

Table 2. Comparison table of specifications

ITEM		Subject Device	Predicate Device K130206	Remark
Product name		Ultrasonic Gastrovideoscope EG-UR5	PENTAX EG-3670URK Ultrasound Video Gastroscope (Radial Array Type)	/
Dimension	Working length	1250mm	1250mm	Similar
	Minimum instrument	Φ2.2mm	Φ2.4mm	

	orifice inner diameter			
	Maximum insertion section outer diameter	Φ12.7mm	Φ13.45mm	
	Outer diameter of main hose	Φ11.5mm	Φ12.1mm	
	Outer diameter of head end	Φ11.3mm	Φ12.0mm	
	Balloon	Yes, detachable	Yes, detachable	
Ultrasound Imaging	Scanning method	Electronic ring scan	Electronic ring scan	Same
	Scanning direction	Perpendicular to insertion direction	Perpendicular to insertion direction	Same
	Scanning angle	360°	360°	Same
	Acoustic Frequency	4.5~12.5 MHz	5-10MHz	similar
	Balloon	Removable	Removable	Same
Endoscope Imaging Systems	Field of view	140° (Direct view mirror)	140° (Direct view mirror)	Same
	Depth of field	3~100mm	4~100mm	Similar
Bend Angulation	Up and down bending angle range	Up：180°，Down：90°	Up：130°，Down：60°	Different
	Left and right bend angle range	Left：100°，Right：100°	Left：60°，Right：60°	
Safety classification	Degree of protection against electric shock	BF type application section	BF type application section	Same

Similar - Dimension

The dimension of the subject device is similar as those the predicate device. The ISO 8600 performance testing has conducted on the subject device and the test result show the performance of the subject device meets the requirements of ISO 8600. Therefore, the difference on dimension will not affect the safety and effectiveness of the subject device.

Similar –Acoustic Frequency

The acoustic frequency range of subject device is similar as that of the predicate device. Based on the acoustic performance comparison testing, the subject device and predicate device are basically the same

based on the comparison of the phantom test on 14 quantitative indexes of ultrasonic imaging performance. Some frequency segments are slightly better or slightly worse, all within the range of measurement error.
Therefore, the difference on acoustic frequency will not affect the safety and effectiveness of the subject device.

Similar- Depth of field
The depth of field of the subject device is similar as the predicate device. However, the depth of field comparison testing has conducted on the subject device and predicate device and the test result show the there is no statistical difference on the performance of the subject device and the predicate device. Therefore, the difference on depth of field will not affect the safety and effectiveness of the subject device.

Different –Bend Angulation
The bend angulation of the subject device is different from the predicate device. The ISO 8600 performance testing has conducted on the subject device and the test result show the performance of the subject device meets the requirements of ISO 8600. Meanwhile, the angulation of the subject device is greater than the predicate device, which provides more operating space for the physician in clinical operation for different situations.
Therefore, the difference on bend angulation will not affect the safety and effectiveness of the subject device.

Table 3. Safety Comparison

ITEM	Subject Device	Predicate Device K130206	Remark
Electrical Safety	Comply with IEC 60601-1	Comply with IEC 60601-1	Same
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Same
Particular requirements	Comply with IEC 60601-2-18 Comply with IEC 60601-2-37	Comply with IEC 60601-2-18 Comply with IEC 60601-2-37	Same
Biocompatibility	No Cytotoxicity	Comply with the ISO 10993 series standards	Same
	No Sensitization		
	No Irritation		

9. Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device, Ultrasonic Gastrovideoscope EG-UR5, is substantially equivalent to the predicate.