

K231813 Ultrasonic GastrovideoscopeMar 8, 2024
261 days to decisionK231813 · Product code: **ODG** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k231813/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Ultrasound System, Gastroenterology-urology (ODG)
Date received	Jun 21, 2023
Decision date	Mar 8, 2024
Days to decision	261 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sonoscape Medical Corp.
Location	Shenzhen, CN
Contact	Toki Wu
510(k) history	24 submissions · 24 cleared · 2015-2025

REGULATORY CONSULTANT

Consulting firm	Mid-Link Consulting Co, Ltd.
Contact	Diana Hong

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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