

K211882 HD-550 Video Endoscope SystemApr 1, 2022
284 days to decisionK211882 · Product code: **NWB** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k211882/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscope, Accessories, Narrow Band Spectrum (NWB)
Date received	Jun 21, 2021
Decision date	Apr 1, 2022
Days to decision	284 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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