

**K231889 Endoscopic Ultrasonic Diagnostic Equipment
/Disposable Sterile Endoscopic Ultrasonic Probe (USW-
S1,USW140-S20MS)**Dec 21, 2023
177 days to decisionK231889 · Product code: **IYO** · Radiology
Source: <https://www.510kdatabase.net/k231889/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Jun 27, 2023
Decision date	Dec 21, 2023
Days to decision	177 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ultrasound Biotechnology (Shanghai) Co., Ltd.
Location	Shanghai, CN
Contact	Yingnan Zhang
510(k) history	1 submissions · 1 cleared · 2023-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231889/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026