

K243880 Shear Wave Quantificational Ultrasound Diagnostic System (Mini900, Mini990, Mini800, Mini790, Mini780, Mini560, Mini300, Mini100, FT100)Jun 17, 2025
181 days to decisionK243880 · Product code: **IYO** · Radiology
Source: <https://www.510kdatabase.net/k243880/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Dec 18, 2024
Decision date	Jun 17, 2025
Days to decision	181 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Wuxi Hisky Medical Technologies Co., Ltd.
Location	Wuxi, CN
Contact	Jinhua Shao
510(k) history	5 submissions · 5 cleared · 2018-2025

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