

**K250026 Shear Wave Quantificational Ultrasound Diagnostic System (FH9000/FH7000/FH6000/FH5000/FH3000/FH1000)**Oct 1, 2025  
268 days to decisionK250026 · Product code: IYN · Radiology  
Source: <https://www.510kdatabase.net/k250026/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Jan 6, 2025
Decision date	Oct 1, 2025
Days to decision	268 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Shenzhen Joyantech Consulting Co., Ltd.</b>
Contact	Siming Wang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k250026/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 14, 2026