

K253487 ACUSON Maple Diagnostic Ultrasound SystemNov 17, 2025
27 days to decisionK253487 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k253487/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Oct 21, 2025
Decision date	Nov 17, 2025
Days to decision	27 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	ACUSON Maple Select Diagnostic Ultrasound System

APPLICANT

Company	Siemens Medical Solutions USA, Inc.
Location	Hoffman Estates, IL, US
Contact	Rapaka Shilpa
510(k) history	778 submissions · 778 cleared · 1980-2026

REGULATORY CONSULTANT

Consulting firm	Regulatory Technology Services, LLC
Contact	Prithul Bom

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

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