

**K200644 ACUSON Freestyle Diagnostic Ultrasound System**Apr 10, 2020  
30 days to decisionK200644 · Product code: IYN · Radiology  
Source: <https://www.510kdatabase.net/k200644/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Mar 11, 2020
Decision date	Apr 10, 2020
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Siemens Medical Solutions USA, Inc.</b>
Location	Hoffman Estates, IL, US
Contact	Shruti Arora
510(k) history	779 submissions · 779 cleared · 1980-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k200644/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 14, 2026