

**K192835 ACUSON NX3 Diagnostic Ultrasound System /  
ACUSON NX3 Elite Diagnostic Ultrasound System**Oct 22, 2019  
20 days to decisionK192835 · Product code: IYN · Radiology  
Source: <https://www.510kdatabase.net/k192835/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Oct 2, 2019
Decision date	Oct 22, 2019
Days to decision	20 days
Third-party review	Yes
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	Hyunjung Lee
510(k) history	779 submissions · 779 cleared · 1980-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Regulatory Technology Services, LLC</b>
Contact	Prithul Bom

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](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k192835/> 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 June 14, 2026