

**K180067 ACUSON X800 Diagnostic Ultrasound System**Feb 7, 2018  
29 days to decisionK180067 · Product code: IYN · Radiology  
Source: <https://www.510kdatabase.net/k180067/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Jan 9, 2018
Decision date	Feb 7, 2018
Days to decision	29 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Siemens Medical Solutions USA, Inc.</b>
Location	Hoffman Estates, IL, US
Contact	Sulgue Choi
510(k) history	778 submissions · 778 cleared · 1980-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k180067/> 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 May 15, 2026