

**K182277 Versana Premier**Nov 21, 2018  
91 days to decisionK182277 · Product code: **IYN** · Radiology  
Source: <https://www.510kdatabase.net/k182277/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Aug 22, 2018
Decision date	Nov 21, 2018
Days to decision	91 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>GE Medical Systems Ultrasound and Primary Care Diagnostics</b>
Location	Wauwatosa, WI, US
Contact	Tracey Ortiz
510(k) history	64 submissions · 64 cleared · 2015-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k182277/> 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