

**K250543 Voluson™ Performance 16**May 29, 2025  
94 days to decisionK250543 · Product code: **IYN** · Radiology  
Source: <https://www.510kdatabase.net/k250543/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Feb 24, 2025
Decision date	May 29, 2025
Days to decision	94 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Voluson™ Performance 18

**APPLICANT**

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

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