

**K163077 LOGIQ E9, LOGIQ E9 XDClear 2.0**Nov 17, 2016  
14 days to decisionK163077 · Product code: IYN · Radiology  
Source: <https://www.510kdatabase.net/k163077/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Nov 3, 2016
Decision date	Nov 17, 2016
Days to decision	14 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	Bryan Behn
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/k163077/> 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 16, 2026