

**K190248 ARIETTA 50**Apr 2, 2019  
54 days to decisionK190248 · Product code: IYN · Radiology  
Source: <https://www.510kdatabase.net/k190248/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Feb 7, 2019
Decision date	Apr 2, 2019
Days to decision	54 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hitachi Healthcare Americas</b>
Location	Twinsburg, OH, US
Contact	Aaron Pierce
510(k) history	12 submissions · 12 cleared · 2018-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k190248/> 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 26, 2026