

K191233 ARIETTA 750Aug 9, 2019
93 days to decisionK191233 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k191233/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	May 8, 2019
Decision date	Aug 9, 2019
Days to decision	93 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191233/> Data sourced from FDA 510(k) public records (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. - Generated May 26, 2026