FDA 510(k) Premarket Notification

K173739 ALOKA ARIETTA 850

CLEARED

Feb 28, 2018
83 days to decision

K173739 · Product code: **IYN** · Radiology
Source: https://www.510kdatabase.net/k173739/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Dec 7, 2017
Decision date	Feb 28, 2018
Days to decision	83 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Hitachi Healthcare Americas Corporation**
Location	Twinsburg, OH, US
Contact	Doug Thistlethwaite
510(k) history	5 submissions · 5 cleared · 2017-2018

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k173739/ 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 16, 2026