FDA 510(k) Premarket Notification

K191233 ARIETTA 750

CLEARED

Aug 9, 2019
93 days to decision

K191233 · 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