FDA 510(k) Premarket Notification

K170858 FDR AQRO (DR-XD 1000)

CLEARED

Apr 24, 2017
33 days to decision

K170858 · Product code: **IZL** · Radiology
Source: https://www.510kdatabase.net/k170858/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Mobile (IZL)
Date received	Mar 22, 2017
Decision date	Apr 24, 2017
Days to decision	33 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Fujifilm Medical Systems U.S.A, Inc.**
Location	Stamford, CT, US
Contact	Peter Altman
510(k) history	39 submissions · 39 cleared · 2005-2018