

K170858 FDR AQRO (DR-XD 1000)Apr 24, 2017
33 days to decisionK170858 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k170858/> 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