

K142003 FDR D-EVO II FLAT PANEL DETECTOR SYSTEMOct 21, 2014
90 days to decisionK142003 · Product code: **MQB** · Radiology
Source: <https://www.510kdatabase.net/k142003/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Solid State X-ray Imager (flat Panel/digital Imager) (MQB)
Date received	Jul 23, 2014
Decision date	Oct 21, 2014
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Fujifilm Medical System U.S.A., Inc.
Location	Stamford, CT, US
Contact	KATHERINE Y CHOI
510(k) history	71 submissions · 71 cleared · 1988-2017

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