

K132509 FDR D-EVO FLAT PANEL DETECTOR SYSTEMNov 25, 2013
105 days to decisionK132509 · Product code: **MQB** · Radiology
Source: <https://www.510kdatabase.net/k132509/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Solid State X-ray Imager (flat Panel/digital Imager) (MQB)
Date received	Aug 12, 2013
Decision date	Nov 25, 2013
Days to decision	105 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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