

K152138 FDR D-EVO GL Flat Panel Detector SystemNov 5, 2015
97 days to decisionK152138 · Product code: **MQB** · Radiology
Source: <https://www.510kdatabase.net/k152138/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Solid State X-ray Imager (flat Panel/digital Imager) (MQB)
Date received	Jul 31, 2015
Decision date	Nov 5, 2015
Days to decision	97 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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