

**K153464 FDR D-EVO flat Panel Detector System**Apr 8, 2016  
129 days to decisionK153464 · Product code: **MQB** · Radiology  
Source: <https://www.510kdatabase.net/k153464/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Solid State X-ray Imager (flat Panel/digital Imager) (MQB)
Date received	Dec 1, 2015
Decision date	Apr 8, 2016
Days to decision	129 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Fujifilm Medical Systems U.S.A, Inc.</b>
Location	Stamford, CT, US
Contact	Katherine Y. Choi
510(k) history	39 submissions · 39 cleared · 2005-2018

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