

**K121499 FUJIFILM TOMOSYNTHESIS OPTION FOR FDR
ACSELERATE STATIONARY X-RAY SYSTEM**

Nov 20, 2012
183 days to decision

K121499 · Product code: **IZF** · Radiology
Source: <https://www.510kdatabase.net/k121499/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomographic (IZF)
Date received	May 21, 2012
Decision date	Nov 20, 2012
Days to decision	183 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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k121499/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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