

K113284 BIOPSY POSITIONERMar 7, 2012
121 days to decisionK113284 · Product code: **IZH** · Radiology
Source: <https://www.510kdatabase.net/k113284/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Mammographic (IZH)
Date received	Nov 7, 2011
Decision date	Mar 7, 2012
Days to decision	121 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Fuji Film Medical Systems
Location	Stamford, CT, US
Contact	KIMERLY A SHARP
510(k) history	1 submissions · 1 cleared · 2012-2012

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