

K152038 MammoGRIPDec 22, 2015
153 days to decisionK152038 · Product code: **IZH** · Radiology
Source: <https://www.510kdatabase.net/k152038/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Mammographic (IZH)
Date received	Jul 22, 2015
Decision date	Dec 22, 2015
Days to decision	153 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Women&apos;S Imaging Solutions Enterprises, LLC
Location	Cresskill, NJ, US
Contact	Nancy DeRobertis
510(k) history	1 submissions · 1 cleared · 2015-2015

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