

K122836 AFFIRM BREAST BIOPSY GUIDANCE SYSTEMJan 11, 2013
116 days to decisionK122836 · Product code: **IZH** · Radiology
Source: <https://www.510kdatabase.net/k122836/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, X-ray, Mammographic (IZH)
Date received	Sep 17, 2012
Decision date	Jan 11, 2013
Days to decision	116 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Lorad, A Hologic Co.
Location	Danbury, CT, US
Contact	GAIL YAEKER-DAUNIS
510(k) history	5 submissions · 5 cleared · 2001-2013

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