

K101373 EMBRACESep 15, 2010
121 days to decisionK101373 · Product code: **IZH** · Radiology
Source: <https://www.510kdatabase.net/k101373/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Mammographic (IZH)
Date received	May 17, 2010
Decision date	Sep 15, 2010
Days to decision	121 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Izi Medical Products, Inc.
Location	Baltimore, MD, US
Contact	HELEN SHAFER
510(k) history	1 submissions · 1 cleared · 2010-2010

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