

K103512 AFFIRM BREAST BIOPSY GUIDANCE SYSTEMJan 7, 2011
38 days to decisionK103512 · Product code: **IZH** · Radiology
Source: <https://www.510kdatabase.net/k103512/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, X-ray, Mammographic (IZH)
Date received	Nov 30, 2010
Decision date	Jan 7, 2011
Days to decision	38 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Hologic, Inc.
Location	Waltham, MA, US
Contact	GAIL YAEKER-DAUNI
Website	https://www.hologic.com/
510(k) history	115 submissions · 111 cleared · 1987-2025

Hologic, Inc. is a medical device company headquartered in Waltham, Massachusetts. The company specializes in women's health, diagnostics, and medical imaging technologies. Hologic has maintained a strong FDA 510(k) regulatory record since its founding in 1987. The company has received FDA 510(k) clearances from total submissions. Recent cleared devices span microbiology, radiology, and obstetrics & gynecology categories. The latest clearance in 2025 demonstrates continued active development and regulatory engagement. Hologic's cleared device portfolio includes molecular ...
