

**K202294 Affirm Contrast Biopsy**Oct 5, 2020  
53 days to decisionK202294 · Product code: **IZH** · Radiology  
Source: <https://www.510kdatabase.net/k202294/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, X-ray, Mammographic (IZH)
Date received	Aug 13, 2020
Decision date	Oct 5, 2020
Days to decision	53 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hologic, Inc.</b>
Location	Waltham, MA, US
Contact	Kate Brown
Website	<a href="https://www.hologic.com/">https://www.hologic.com/</a>
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 ...

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