

**K230096 Genius AI Detection 2.0 with CC-MLO Correlation**May 23, 2023  
130 days to decisionK230096 · Product code: **QDQ** · Radiology  
Source: <https://www.510kdatabase.net/k230096/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer Assisted Detection/diagnosis Software For Lesions Suspicious For Cancer (QDQ)
Date received	Jan 13, 2023
Decision date	May 23, 2023
Days to decision	130 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hologic, Inc.</b>
Location	Waltham, MA, US
Contact	Deborah Thomas
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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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k230096/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).

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