

**K150169 Sertera Biopsy Device**Aug 14, 2015  
200 days to decisionK150169 · Product code: **KNW** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k150169/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy (KNW)
Date received	Jan 26, 2015
Decision date	Aug 14, 2015
Days to decision	200 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hologic, Inc.</b>
Location	Waltham, MA, US
Contact	Brenda Geary
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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