

**K100943 INVADER FACTOR II**Jun 2, 2011  
422 days to decisionK100943 · Product code: **NPR** · Pathology  
Source: <https://www.510kdatabase.net/k100943/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Factor Ii G20210a Mutations, Genomic Dna Pcr (NPR)
Date received	Apr 6, 2010
Decision date	Jun 2, 2011
Days to decision	422 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hologic, Inc.</b>
Location	Waltham, MA, US
Contact	RANDALL COVILL
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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