

K100496 INVADER MTHFR 1298Apr 25, 2011
427 days to decisionK100496 · Product code: **OMM** · Pathology
Source: <https://www.510kdatabase.net/k100496/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test 5, 10-methylenetetrahydrofolate Reductase Mutations, Genomic Dna Pcr (OMM)
Date received	Feb 22, 2010
Decision date	Apr 25, 2011
Days to decision	427 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Hologic, Inc.
Location	Waltham, MA, US
Contact	RANDALL J COVILL
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 ...