

K191281 Omni Hysteroscope, Omni Lok cervical sealAug 29, 2019
108 days to decisionK191281 · Product code: **HIH** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k191281/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hysteroscope (and Accessories) (HIH)
Date received	May 13, 2019
Decision date	Aug 29, 2019
Days to decision	108 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hologic, Inc.
Location	Waltham, MA, US
Contact	Rachelle D. Fitzgerald
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 ...

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Device record: <https://www.510kdatabase.net/k191281/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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