

K182006 Omni Hysteroscope, Omni Hysteroscope Kits, Omni SheathsDec 6, 2018
132 days to decisionK182006 · Product code: **HIH** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k182006/>**SUBMISSION DETAILS**

| | |
|-----------------------|--------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Hysteroscope (and Accessories) (HIH) |
| Date received | Jul 27, 2018 |
| Decision date | Dec 6, 2018 |
| Days to decision | 132 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 ...