FDA 510(k) Premarket Notification

CLEARED

K172566 Myosure Hysteroscopic Tissue Removal System and Myosure Tissue Removal Devices

Sep 20, 2017
26 days to decision

K172566 · Product code: **HIH** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k172566/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Hysteroscope (and Accessories) (HIH)
Date received	Aug 25, 2017
Decision date	Sep 20, 2017
Days to decision	26 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Hologic, Inc.**
Location	Waltham, MA, US
Contact	Catherine Sanford
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 ...