FDA 510(k) Premarket Notification

CLEARED

K240886 Fluent Pro Fluid Management System (FLT-200)

Jul 25, 2024
115 days to decision

K240886 · Product code: **HIG** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k240886/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Insufflator, Hysteroscopic (HIG)
Date received	Apr 1, 2024
Decision date	Jul 25, 2024
Days to decision	115 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Fluent Pro Fluid Management System Disposable Procedure Kit (6-pack) (FLT-212); Fluent Pro Fluid Management System Disposable Procedure Kit (1-pack) (FLT-212S); Fluent Pro Fluid Management System Tissue Trap Multipack (10-pack) (FLT-210); Fluent Pro Fluid Management System Waste Bag Multipack (5-pack) (FLT-205)

APPLICANT

Company	**Hologic, Inc.**
Location	Waltham, MA, US
Contact	Meghan Wakeford
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 ...