

K971188 SMITH & NEPHEW IMAGES ENDOSCOPES AND ACCESSORIS/SEMI-RIGID AND FLEXIBLE MANUAL INSTRUMENTS

Jun 27, 1997
88 days to decision

K971188 · Product code: **HIH** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k971188/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hysteroscope (and Accessories) (HIH)
Date received	Mar 31, 1997
Decision date	Jun 27, 1997
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Smith & Nephew, Inc.
Location	Mchenry, IL, US
Contact	ELIZABETH A RYAN
Website	http://www.smith-nephew.com/
510(k) history	530 submissions · 517 cleared · 1980-2026

Smith & Nephew, Inc. is a medical technology company focused on repair, regeneration, and replacement of soft and hard tissues. The company operates with a manufacturing facility in McHenry, US. Smith & Nephew has established a significant regulatory track record with the FDA. The company has received FDA 510(k) clearances from total submissions since 1980. Orthopedic devices represent the dominant category, accounting for 71% of submissions. The company remains active, with the latest clearance in 2025. Recent cleared devices reflect a strong focus on orthopedic surgical...