

**K013870 SMITH & NEPHEW OPERATIVE HYSTEROSCOPE,
MODEL 7209208**Jan 17, 2002
57 days to decisionK013870 · Product code: **HIH** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k013870/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hysteroscope (and Accessories) (HIH)
Date received	Nov 21, 2001
Decision date	Jan 17, 2002
Days to decision	57 days
Third-party review	No
Summary / Statement	Summary
Other names	SMITH & NEPHEW CONTINUOUS FLOW SHEATH, MODEL 8105224

APPLICANT

Company	Smith & Nephew, Inc.
Location	Mchenry, IL, US
Contact	JANICE HASELTON
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...