FDA 510(k) Premarket Notification

CLEARED

K161763 Smith & Nephew TRUCLEAR ULTRA Mini Tissue Removal Device

Nov 22, 2016
148 days to decision

K161763 · Product code: **HIH** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k161763/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hysteroscope (and Accessories) (HIH)
Date received	Jun 27, 2016
Decision date	Nov 22, 2016
Days to decision	148 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Smith & Nephew, Inc.**
Location	Mchenry, IL, US
Contact	Bradley Heil
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...