FDA 510(k) Premarket Notification

CLEARED

K994084 SMITH & NEPHEW XENON LIGHT SOURCES AND ACCESSORIES

Jan 20, 2000
48 days to decision

K994084 · Product code: **FFS** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k994084/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Image, Illumination, Fiberoptic, For Endoscope (FFS)
Date received	Dec 3, 1999
Decision date	Jan 20, 2000
Days to decision	48 days
Third-party review	No
Summary / Statement	Summary

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...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k994084/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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