FDA 510(k) Premarket Notification

K940222 SMITH AND NEPHEW SPINE DEFLECTING FORCEPS

CLEARED

Jun 29, 1994
162 days to decision

K940222 · Product code: **HRX** · Orthopedic
Source: https://www.510kdatabase.net/k940222/

SUBMISSION DETAILS

Decision	Substantially Equivalent - SN
Submission type	Traditional
Device classification	Arthroscope (HRX)
Date received	Jan 18, 1994
Decision date	Jun 29, 1994
Days to decision	162 days
Third-party review	No

APPLICANT

Company	**Smith & Nephew, Inc.**
Location	Mchenry, IL, US
Contact	NEAL DEFIBAUGH
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...