FDA 510(k) Premarket Notification

K864307 MAX-I-PROBE PERIDONTAL/ENDODONTIC PROBE(TM) (MODI)

CLEARED

Nov 18, 1986
15 days to decision

K864307 · Product code: **EIC** · Dental
Source: https://www.510kdatabase.net/k864307/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Periodontic, Endodontic, Irrigating (EIC)
Date received	Nov 3, 1986
Decision date	Nov 18, 1986
Days to decision	15 days
Third-party review	No

APPLICANT

Company	**Smith & Nephew, Inc.**
Location	Mchenry, IL, US
Contact	JAMES F PRINCE
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...