FDA 510(k) Premarket Notification

K970533 MODEL 1100 COLD THERAPY DEVICE

CLEARED

Apr 15, 1997
62 days to decision

K970533 · Product code: **ILO** · Physical Medicine
Source: https://www.510kdatabase.net/k970533/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pack, Hot Or Cold, Water Circulating (ILO)
Date received	Feb 12, 1997
Decision date	Apr 15, 1997
Days to decision	62 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Smith & Nephew, Inc.**
Location	Mchenry, IL, US
Contact	DAN W MILLER
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/k970533/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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