FDA 510(k) Premarket Notification

K991957 CICACARE MANAGEMENT FOR SCARS

CLEARED

Jul 20, 1999
40 days to decision

K991957 · Product code: **MDA** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k991957/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Elastomer, Silicone, For Scar Management (MDA)
Date received	Jun 10, 1999
Decision date	Jul 20, 1999
Days to decision	40 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Smith & Nephew, Inc.**
Location	Mchenry, IL, US
Contact	JIM IRVIN
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...