FDA 510(k) Premarket Notification

CLEARED

K972471 DIGITAL 3-CHIP COLOR VIDEO CAMERA, ILLUMINATORS, VIDEO COMPONENTS AND ACCESSORIES

Oct 24, 1997
115 days to decision

K972471 · Product code: **GCJ** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k972471/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Jul 1, 1997
Decision date	Oct 24, 1997
Days to decision	115 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Smith & Nephew, Inc.**
Location	Mchenry, IL, US
Contact	DEBORAH J CONNORS
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/k972471/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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