FDA 510(k) Premarket Notification

K201349 Smith+Nephew Arthroscopes

CLEARED

Jul 20, 2020
60 days to decision

K201349 · Product code: **HRX** · Orthopedic
Source: https://www.510kdatabase.net/k201349/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Arthroscope (HRX)
Date received	May 21, 2020
Decision date	Jul 20, 2020
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Smith & Nephew**
Location	Memphis, TN, US
Contact	Katheen Solomon
Website	http://www.smith-nephew.com/
510(k) history	17 submissions · 17 cleared · 2015-2025

Smith & Nephew is a medical technology company focused on repair, regeneration, and replacement of soft and hard tissues. The company operates with a manufacturing facility in Memphis, US, and serves approximately 100 countries worldwide. The company has received FDA 510(k) clearances from total submissions since 2015. Orthopedic devices represent the dominant category, including pelvic and acetabular systems, patella plates, suture anchors, cable systems, external fixators, arthroscopes, and limb lengthening systems. The latest clearance was granted in 2025, confirming a...