FDA 510(k) Premarket Notification

CLEARED

K946313 TIBIAL ROUTERS, FEMORAL ROUTERS AND TUBE GRAFT SIZER

Mar 17, 1995
79 days to decision

K946313 · Product code: **HRX** · Orthopedic
Source: https://www.510kdatabase.net/k946313/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Arthroscope (HRX)
Date received	Dec 28, 1994
Decision date	Mar 17, 1995
Days to decision	79 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Smith and Nephew Donjoy, Inc.**
Location	Carsbad, CA, US
Contact	DAN W MILLER
510(k) history	15 submissions · 12 cleared · 1991-1997