FDA 510(k) Premarket Notification

K013117 RESECTION ABLATOR

CLEARED

Nov 29, 2001
72 days to decision

K013117 · Product code: **HRX** · Orthopedic
Source: https://www.510kdatabase.net/k013117/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Arthroscope (HRX)
Date received	Sep 18, 2001
Decision date	Nov 29, 2001
Days to decision	72 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Linvatec Corp.**
Location	Research Triangle Pa, NC, US
Contact	LAURA D SENEFF
510(k) history	93 submissions · 87 cleared · 1992-2009