FDA 510(k) Premarket Notification

K943985 LIMITED REUSE BLADES

CLEARED

Nov 7, 1994
83 days to decision

K943985 · Product code: **HRX** · Orthopedic
Source: https://www.510kdatabase.net/k943985/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Arthroscope (HRX)
Date received	Aug 16, 1994
Decision date	Nov 7, 1994
Days to decision	83 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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