

K943985 LIMITED REUSE BLADESNov 7, 1994
83 days to decisionK943985 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k943985/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026