

K941691 REVO ROTATOR CUFF REPAIR SYSTEMSep 6, 1994
153 days to decisionK941691 · Product code: **HRX** · Orthopedic
Source: <https://www.510kdatabase.net/k941691/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Arthroscope (HRX)
Date received	Apr 6, 1994
Decision date	Sep 6, 1994
Days to decision	153 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k941691/> 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