

K943356 INCLUSIVE ENDOSCOPEMay 10, 1995
302 days to decisionK943356 · Product code: **HRX** · Orthopedic
Source: <https://www.510kdatabase.net/k943356/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Arthroscope (HRX)
Date received	Jul 12, 1994
Decision date	May 10, 1995
Days to decision	302 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Danek Medical, Inc.
Location	Mchenry, IL, US
Contact	RICHARD W TREHARNE
510(k) history	56 submissions · 47 cleared · 1981-2000

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k943356/> 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 21, 2026