FDA 510(k) Premarket Notification

K994425 MODIFICATION TO ENDOSCOPIC SPINAL ACCESS SYSTEM

CLEARED

Feb 16, 2000
48 days to decision

K994425 · Product code: **HRX** · Orthopedic
Source: https://www.510kdatabase.net/k994425/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Arthroscope (HRX)
Date received	Dec 30, 1999
Decision date	Feb 16, 2000
Days to decision	48 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Endius, Inc.**
Location	Plainville, MA, US
Contact	SUSAN FINNERAN
510(k) history	33 submissions · 33 cleared · 1997-2008