FDA 510(k) Premarket Notification

K061345 MODIFICATION TO ENDIUS ATAVI SYSTEM

CLEARED

Jun 6, 2006
22 days to decision

K061345 · Product code: **HRX** · Orthopedic
Source: https://www.510kdatabase.net/k061345/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Arthroscope (HRX)
Date received	May 15, 2006
Decision date	Jun 6, 2006
Days to decision	22 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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