FDA 510(k) Premarket Notification

K022364 NAVITRACK SYSTEM TOTAL HIP REPLACEMENT,MODEL 900.200

CLEARED

Feb 4, 2003
197 days to decision

K022364 · Product code: **HAW** · Neurology
Source: https://www.510kdatabase.net/k022364/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Jul 22, 2002
Decision date	Feb 4, 2003
Days to decision	197 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Orthosoft, Inc.**
Location	Montreal, Quebec, CA
Contact	CHRISTOPHER MCLEAN
510(k) history	14 submissions · 14 cleared · 1998-2013