FDA 510(k) Premarket Notification

K960537 K2 BONE SCREW SYSTEM

CLEARED

Mar 25, 1996
47 days to decision

K960537 · Product code: **HWC** · Orthopedic
Source: https://www.510kdatabase.net/k960537/

SUBMISSION DETAILS

Decision	Substantially Equivalent - SN
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Feb 7, 1996
Decision date	Mar 25, 1996
Days to decision	47 days
Third-party review	No

APPLICANT

Company	**Kinetikos Medical, Inc.**
Location	San Diego, CA, US
Contact	MARK G URBANSKI
510(k) history	19 submissions · 16 cleared · 1994-2006