FDA 510(k) Premarket Notification

K091686 LEFORTE NEUROSYSTEM BONE SCREW

CLEARED

Nov 13, 2009
157 days to decision

K091686 · Product code: **HWC** · Orthopedic
Source: https://www.510kdatabase.net/k091686/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Jun 9, 2009
Decision date	Nov 13, 2009
Days to decision	157 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Jeil Medical Corporation**
Location	Deer Field, IL, US
Contact	SHIN KUK YOO
510(k) history	53 submissions · 53 cleared · 2002-2026