

K091686 LEFORTE NEUROSYSYSTEM BONE SCREWNov 13, 2009
157 days to decisionK091686 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k091686/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 19, 2026