

K120419 DYNA LOCKING ANKLE NAILMay 21, 2012
101 days to decisionK120419 · Product code: **HSB** · Orthopedic
Source: <https://www.510kdatabase.net/k120419/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rod, Fixation, Intramedullary And Accessories (HSB)
Date received	Feb 10, 2012
Decision date	May 21, 2012
Days to decision	101 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	U&I Corp.
Location	Uijungbu, Gyeonggi-Do, KR
Contact	GYEONG-JE KWON
510(k) history	12 submissions · 12 cleared · 2005-2014

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k120419/> 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 17, 2026