

K190231 InCore® Lapidus Sterile KitsMay 24, 2019
107 days to decisionK190231 · Product code: **HWC** · Orthopedic
Source: <https://www.510kdatabase.net/k190231/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Feb 6, 2019
Decision date	May 24, 2019
Days to decision	107 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Nextremity Solutions, Inc.
Location	Red Bank, NJ, US
Contact	Greg Denham
510(k) history	17 submissions · 17 cleared · 2014-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k190231/> 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 26, 2026