

K182342 IntraLock Lapidus SystemMay 21, 2019
266 days to decisionK182342 · Product code: **HWC** · Orthopedic
Source: <https://www.510kdatabase.net/k182342/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Aug 28, 2018
Decision date	May 21, 2019
Days to decision	266 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Fusion Orthopedics, LLC
Location	Mesa, AZ, US
Contact	Eli Jacobson
510(k) history	11 submissions · 11 cleared · 2016-2021

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k182342/> 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 27, 2026