

K152370 PRECICE Trauma Nail SystemDec 22, 2015
123 days to decisionK152370 · Product code: **HSB** · Orthopedic
Source: <https://www.510kdatabase.net/k152370/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Rod, Fixation, Intramedullary And Accessories (HSB)
Date received	Aug 21, 2015
Decision date	Dec 22, 2015
Days to decision	123 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ellipse Technologies, Incorporated
Location	Irvine, CA, US
Contact	John McIntyre
510(k) history	7 submissions · 7 cleared · 2015-2016

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k152370/> 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