

K160325 PRECICE Intramedullary Limb Lengthening SystemApr 4, 2016
59 days to decisionK160325 · Product code: **HSB** · Orthopedic
Source: <https://www.510kdatabase.net/k160325/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rod, Fixation, Intramedullary And Accessories (HSB)
Date received	Feb 5, 2016
Decision date	Apr 4, 2016
Days to decision	59 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ellipse Technologies, Inc.
Location	Irvine, CA, US
Contact	Cora Sim
510(k) history	13 submissions · 13 cleared · 2011-2016

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k160325/> 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