

K160545 GAP ENDO-EXO MEDULLARY SYSTEMNov 23, 2016
271 days to decisionK160545 · Product code: **HSB** · Orthopedic
Source: <https://www.510kdatabase.net/k160545/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rod, Fixation, Intramedullary And Accessories (HSB)
Date received	Feb 26, 2016
Decision date	Nov 23, 2016
Days to decision	271 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Pega Medical, Inc.
Location	Quebec, CA
Contact	Ariel R. Dujovne
510(k) history	12 submissions · 12 cleared · 2003-2022

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