

K111232 GAP ENDO-EXO MEDULLARY SYSTEMJan 26, 2012
269 days to decisionK111232 · Product code: **HSB** · Orthopedic
Source: <https://www.510kdatabase.net/k111232/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rod, Fixation, Intramedullary And Accessories (HSB)
Date received	May 2, 2011
Decision date	Jan 26, 2012
Days to decision	269 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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