

K211292 Fassier-Duval Telescopic IM SystemMay 26, 2021
28 days to decisionK211292 · Product code: **HSB** · Orthopedic
Source: <https://www.510kdatabase.net/k211292/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Rod, Fixation, Intramedullary And Accessories (HSB)
Date received	Apr 28, 2021
Decision date	May 26, 2021
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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