

**K192710 The Simple Locking Intramedullary (Slim) System**Jun 24, 2020  
271 days to decisionK192710 · Product code: **HSB** · Orthopedic  
Source: <https://www.510kdatabase.net/k192710/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rod, Fixation, Intramedullary And Accessories (HSB)
Date received	Sep 27, 2019
Decision date	Jun 24, 2020
Days to decision	271 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k192710/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026