

K163003 Y3 Proximal Femoral Plate SystemMar 16, 2017
139 days to decisionK163003 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k163003/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Oct 28, 2016
Decision date	Mar 16, 2017
Days to decision	139 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k163003/> 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 26, 2026