

K160791 AmorChem Titanium Porous Fixation DeviceNov 15, 2016
237 days to decisionK160791 · Product code: **HWC** · Orthopedic
Source: <https://www.510kdatabase.net/k160791/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Mar 23, 2016
Decision date	Nov 15, 2016
Days to decision	237 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Amorchem Holdings, Inc.
Location	Montreal, CA
Contact	KEVIN MCBRIDE
510(k) history	1 submissions · 1 cleared · 2016-2016

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k160791/> 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 16, 2026