FDA 510(k) Premarket Notification

K071377 POLARIS BE RODS

CLEARED

Aug 6, 2007
81 days to decision

K071377 · Product code: **KWP** · Orthopedic
Source: https://www.510kdatabase.net/k071377/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Interlaminal (KWP)
Date received	May 17, 2007
Decision date	Aug 6, 2007
Days to decision	81 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Biomet Spine**
Location	Warsaw, IN, US
Contact	DEBRA BING
510(k) history	19 submissions · 18 cleared · 2007-2016

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k071377/ 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 17, 2026