

K994217 BLACKSTONE SPINAL FIXATION SYSTEMFeb 28, 2000
75 days to decisionK994217 · Product code: **MNH** · Orthopedic
Source: <https://www.510kdatabase.net/k994217/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Spondylolisthesis Spinal Fixation (MNH)
Date received	Dec 15, 1999
Decision date	Feb 28, 2000
Days to decision	75 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Blackstone Medical, Inc.
Location	Springfield, MA, US
Contact	ALAN LOMBARDO
510(k) history	45 submissions · 45 cleared · 1997-2010

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k994217/> 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 19, 2026