

**K013558 BLACKSTONE SPINAL FIXATION SYSTEM 4.5MM  
MONO-AXIAL SCREW**Jan 23, 2002  
90 days to decisionK013558 · Product code: **KWQ** · Orthopedic  
Source: <https://www.510kdatabase.net/k013558/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Oct 25, 2001
Decision date	Jan 23, 2002
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k013558/> 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