

**K030581 BLACKSTONE SPINAL FIXATION SYSTEM LATERAL  
OFFSET (SYSTEM MODIFICATION)**

Jun 26, 2003  
122 days to decision

K030581 · Product code: **MNH** · Orthopedic  
Source: <https://www.510kdatabase.net/k030581/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthosis, Spondylolisthesis Spinal Fixation (MNH)
Date received	Feb 24, 2003
Decision date	Jun 26, 2003
Days to decision	122 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k030581/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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