

K042514 MODIFICATION TO BLACKSTONE MODULAR PEDICLE SCREW SYSTEM

Oct 7, 2004
21 days to decision

K042514 · Product code: MNI · Orthopedic
Source: <https://www.510kdatabase.net/k042514/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthosis, Spinal Pedicle Fixation (MNI)
Date received	Sep 16, 2004
Decision date	Oct 7, 2004
Days to decision	21 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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Device record: <https://www.510kdatabase.net/k042514/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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