

**K083635 SMITH & NEPHEW BIOSURE PK INTERFERENCE
SCREW**Jan 30, 2009
53 days to decisionK083635 · Product code: **MBI** · Orthopedic
Source: <https://www.510kdatabase.net/k083635/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Dec 8, 2008
Decision date	Jan 30, 2009
Days to decision	53 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Smith & Nephew Endoscopy, Inc.
Location	Andover, MA, US
Contact	CHRISTINA FLORES
510(k) history	18 submissions · 17 cleared · 1996-2011

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