

**K983258 MODIFICATION TO SPINAL CONCEPTS BACFIX
SPINAL FIXATION SYSTEM**Oct 21, 1998
35 days to decisionK983258 · Product code: **MNI** · Orthopedic
Source: <https://www.510kdatabase.net/k983258/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Spinal Pedicle Fixation (MNI)
Date received	Sep 16, 1998
Decision date	Oct 21, 1998
Days to decision	35 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Spinal Concepts, Inc.
Location	Austin, TX, US
Contact	TEENA M AUGOSTINO
510(k) history	33 submissions · 28 cleared · 1997-2005

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k983258/> 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 20, 2026