

K993402 OPUS SPINAL SYSTEMDec 20, 1999
73 days to decisionK993402 · Product code: **MNI** · Orthopedic
Source: <https://www.510kdatabase.net/k993402/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Spinal Pedicle Fixation (MNI)
Date received	Oct 8, 1999
Decision date	Dec 20, 1999
Days to decision	73 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Howmedica Osteonics Corp.
Location	Allendale, NJ, US
Contact	MARY-CATHERINE DILLON
510(k) history	288 submissions · 288 cleared · 1999-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k993402/> 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 16, 2026