

**K000991 MODIFICATION TO TSRH SPINAL SYSTEM**Apr 18, 2000  
21 days to decisionK000991 · Product code: **MNI** · Orthopedic  
Source: <https://www.510kdatabase.net/k000991/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthosis, Spinal Pedicle Fixation (MNI)
Date received	Mar 28, 2000
Decision date	Apr 18, 2000
Days to decision	21 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Medtronic Sofamor Danek, Inc.</b>
Location	Memphis, TN, US
Contact	RICHARD W TREHARNE
510(k) history	99 submissions · 89 cleared · 2000-2025

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k000991/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 17, 2026