

K011067 MODIFICATION TO TSRH SPINAL SYSTEMMay 4, 2001
25 days to decisionK011067 · Product code: **MNI** · Orthopedic
Source: <https://www.510kdatabase.net/k011067/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthosis, Spinal Pedicle Fixation (MNI)
Date received	Apr 9, 2001
Decision date	May 4, 2001
Days to decision	25 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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