

K984522 MODIFICATION OF TSRH SPINAL SYSTEMJan 6, 1999
16 days to decisionK984522 · Product code: **MNI** · Orthopedic
Source: <https://www.510kdatabase.net/k984522/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthosis, Spinal Pedicle Fixation (MNI)
Date received	Dec 21, 1998
Decision date	Jan 6, 1999
Days to decision	16 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Danek Medical, Inc.
Location	Mchenry, IL, US
Contact	RICHARD W TREHARNE
510(k) history	56 submissions · 47 cleared · 1981-2000

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