

K053483 MODIFICATION TO VERTEX RECONSTRUCTION SYSTEMJan 5, 2006
21 days to decisionK053483 · Product code: **MNI** · Orthopedic
Source: <https://www.510kdatabase.net/k053483/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthosis, Spinal Pedicle Fixation (MNI)
Date received	Dec 15, 2005
Decision date	Jan 5, 2006
Days to decision	21 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medtronic Sofamor Danek
Location	Memphis, TN, US
Contact	RICHARD TREHARNE
510(k) history	154 submissions · 147 cleared · 2002-2021

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k053483/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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