FDA 510(k) Premarket Notification

K053483 MODIFICATION TO VERTEX RECONSTRUCTION SYSTEM

CLEARED

Jan 5, 2006
21 days to decision

K053483 · 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