FDA 510(k) Premarket Notification

K023555 MODIFICATION TO VERTEX RECONSTRUCTION SYSTEM

CLEARED

Nov 22, 2002
30 days to decision

K023555 · Product code: **KWP** · Orthopedic
Source: https://www.510kdatabase.net/k023555/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Appliance, Fixation, Spinal Interlaminal (KWP)
Date received	Oct 23, 2002
Decision date	Nov 22, 2002
Days to decision	30 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