FDA 510(k) Premarket Notification

K022015 MODIFICATION TO VERTEX RECONSTRUCTION SYSTEM

CLEARED

Jul 18, 2002
28 days to decision

K022015 · Product code: **KWP** · Orthopedic
Source: https://www.510kdatabase.net/k022015/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Appliance, Fixation, Spinal Interlaminal (KWP)
Date received	Jun 20, 2002
Decision date	Jul 18, 2002
Days to decision	28 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