FDA 510(k) Premarket Notification

K003780 VERTEX RECONSTRUCTION SYSTEM

CLEARED

Sep 28, 2001
295 days to decision

K003780 · Product code: **KWP** · Orthopedic
Source: https://www.510kdatabase.net/k003780/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Interlaminal (KWP)
Date received	Dec 7, 2000
Decision date	Sep 28, 2001
Days to decision	295 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