FDA 510(k) Premarket Notification

K121191 VERTEX RCONSTRUCTION SYSTEM

CLEARED

Jun 29, 2012
71 days to decision

K121191 · Product code: **KWP** · Orthopedic
Source: https://www.510kdatabase.net/k121191/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Interlaminal (KWP)
Date received	Apr 19, 2012
Decision date	Jun 29, 2012
Days to decision	71 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medtronic Sofamor Danek, Inc.**
Location	Memphis, TN, US
Contact	CLAIRE EVANS
510(k) history	99 submissions · 89 cleared · 2000-2025