FDA 510(k) Premarket Notification

K052734 MODIFICATION TO: VERTEX RECONSTRUCTION SYSTEM

CLEARED

Oct 21, 2005
21 days to decision

K052734 · Product code: **KWP** · Orthopedic
Source: https://www.510kdatabase.net/k052734/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Appliance, Fixation, Spinal Interlaminal (KWP)
Date received	Sep 30, 2005
Decision date	Oct 21, 2005
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