FDA 510(k) Premarket Notification

K052376 MODIFICATION TO: VERTEX RECONSTRUCTION SYSTEM

CLEARED

Sep 23, 2005
24 days to decision

K052376 · Product code: **KWP** · Orthopedic
Source: https://www.510kdatabase.net/k052376/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Appliance, Fixation, Spinal Interlaminal (KWP)
Date received	Aug 30, 2005
Decision date	Sep 23, 2005
Days to decision	24 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