FDA 510(k) Premarket Notification

K052180 MODIFICATION TO VERTEX RECONSTRUCTION SYSTEM

CLEARED

Aug 23, 2005
13 days to decision

K052180 · Product code: **KWP** · Orthopedic
Source: https://www.510kdatabase.net/k052180/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Appliance, Fixation, Spinal Interlaminal (KWP)
Date received	Aug 10, 2005
Decision date	Aug 23, 2005
Days to decision	13 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