FDA 510(k) Premarket Notification

K071942 MODIFICATION TO VERTEX RECONSTRUCTION SYSTEM

CLEARED

Dec 11, 2007
151 days to decision

K071942 · Product code: **KWP** · Orthopedic
Source: https://www.510kdatabase.net/k071942/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Interlaminal (KWP)
Date received	Jul 13, 2007
Decision date	Dec 11, 2007
Days to decision	151 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medtronic Sofamor Danek**
Location	Memphis, TN, US
Contact	MICHELLE WILLIS
510(k) history	154 submissions · 147 cleared · 2002-2021