FDA 510(k) Premarket Notification

K070742 MODIFICATION TO VERTEX RECONSTRUCTION SYSTEM

CLEARED

Sep 14, 2007
182 days to decision

K070742 · Product code: **KWP** · Orthopedic
Source: https://www.510kdatabase.net/k070742/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Interlaminal (KWP)
Date received	Mar 16, 2007
Decision date	Sep 14, 2007
Days to decision	182 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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