FDA 510(k) Premarket Notification

K080805 MODIFICATION TO VERTEX RECONSTRUCTION SYSTEM

CLEARED

Apr 18, 2008
28 days to decision

K080805 · Product code: **KWP** · Orthopedic
Source: https://www.510kdatabase.net/k080805/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Appliance, Fixation, Spinal Interlaminal (KWP)
Date received	Mar 21, 2008
Decision date	Apr 18, 2008
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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