FDA 510(k) Premarket Notification

K091365 VERTEX RECONSTRUCTION SYSTEM, VERTEX SELECT RECONSTRUCTION SYSTEM

CLEARED

Aug 6, 2009
90 days to decision

K091365 · Product code: **KWP** · Orthopedic
Source: https://www.510kdatabase.net/k091365/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Interlaminal (KWP)
Date received	May 8, 2009
Decision date	Aug 6, 2009
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medtronic Soafamor Danek**
Location	Memphis, TN, US
Contact	MELISA LANSKY
510(k) history	1 submissions · 1 cleared · 2009-2009