FDA 510(k) Premarket Notification

K082728 VERTEX RECONTRUCTION SYSTEM, VERTEX SELECT RECONSTRUCTION SYSTEM

CLEARED

Jan 16, 2009
120 days to decision

K082728 · Product code: **KWP** · Orthopedic
Source: https://www.510kdatabase.net/k082728/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Interlaminal (KWP)
Date received	Sep 18, 2008
Decision date	Jan 16, 2009
Days to decision	120 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medtronic Sofamor Danek USA, Inc.**
Location	Memphis, TN, US
Contact	MELISA LANSKY
510(k) history	170 submissions · 159 cleared · 2000-2026