FDA 510(k) Premarket Notification

K113529 CD HORIZON VOYAGER SPINAL SYSTEM

CLEARED

Feb 9, 2012
71 days to decision

K113529 · Product code: **NKB** · Orthopedic
Source: https://www.510kdatabase.net/k113529/

SUBMISSION DETAILS

Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Nov 30, 2011
Decision date	Feb 9, 2012
Days to decision	71 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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