FDA 510(k) Premarket Notification

K132328 CD HORIZON SPINAL SYSTEM

CLEARED

Dec 6, 2013
133 days to decision

K132328 · Product code: **NKB** · Orthopedic
Source: https://www.510kdatabase.net/k132328/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Jul 26, 2013
Decision date	Dec 6, 2013
Days to decision	133 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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