FDA 510(k) Premarket Notification

K091974 MODIFICATION TO CD HORIZON SPINAL SYSTEM

CLEARED

Sep 2, 2009
63 days to decision

K091974 · Product code: **NKB** · Orthopedic
Source: https://www.510kdatabase.net/k091974/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Jul 1, 2009
Decision date	Sep 2, 2009
Days to decision	63 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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