

K121764 CD HORIZON SPINAL SYSTEMAug 21, 2012
67 days to decisionK121764 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k121764/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - U
Submission type	Special
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Jun 15, 2012
Decision date	Aug 21, 2012
Days to decision	67 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medtronic Sofamor Danek, Inc.
Location	Memphis, TN, US
Contact	BRAD SHEALS
510(k) history	99 submissions · 89 cleared · 2000-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k121764/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 16, 2026