

**K153442 CD HORIZON Spinal System, Medtronic Navigated Manual Reusable Instruments for Use with the STEALTHSTATION System, Medtronic Reusable Instruments for Use with the IPC POWEREASE System, Medtronic Navigated Reusable Instruments for Use with the STEALTHSTATION and IPC POWEREASE Systems**

Feb 18, 2016  
83 days to decision

K153442 · Product code: **NKB** · Orthopedic  
Source: <https://www.510kdatabase.net/k153442/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Nov 27, 2015
Decision date	Feb 18, 2016
Days to decision	83 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medtronic Sofamor Danek USA, Inc.</b>
Location	Memphis, TN, US
Contact	Lila Joe
510(k) history	170 submissions · 159 cleared · 2000-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k153442/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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