

K081080 TSRH SPINAL SYSTEMNov 21, 2008
219 days to decisionK081080 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k081080/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Apr 16, 2008
Decision date	Nov 21, 2008
Days to decision	219 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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