

K091797 TSRH SPINAL SYSTEMApr 30, 2010
317 days to decisionK091797 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k091797/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Jun 17, 2009
Decision date	Apr 30, 2010
Days to decision	317 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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