

**K012081 DYNAMIC COMPRESSION SHAPE MEMORY ALLOY  
(SMA) STAPLE SYSTEM**Oct 1, 2001  
90 days to decisionK012081 · Product code: JDR · Orthopedic  
Source: <https://www.510kdatabase.net/k012081/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Staple, Fixation, Bone (JDR)
Date received	Jul 3, 2001
Decision date	Oct 1, 2001
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medtronic Sofamor Danek, Inc.</b>
Location	Memphis, TN, US
Contact	RICHARD TREHARNE
510(k) history	99 submissions · 89 cleared · 2000-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k012081/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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