

K946348 TITANIUM TSRH(R) SPINAL SYSTEM (SCREWS)Aug 7, 1995
220 days to decisionK946348 · Product code: **MNH** · Orthopedic
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Decision	Substantially Equivalent - SN
Submission type	Traditional
Device classification	Orthosis, Spondylolisthesis Spinal Fixation (MNH)
Date received	Dec 30, 1994
Decision date	Aug 7, 1995
Days to decision	220 days
Third-party review	No

APPLICANT

Company	Sofamor Danek USA, Inc.
Location	Memphis, TN, US
Contact	RICHARD W TREHARNE
510(k) history	41 submissions · 26 cleared · 1995-2000

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