

K984360 COLORADO II SPINAL SYSTEMMar 30, 2000
479 days to decisionK984360 · Product code: **MNH** · Orthopedic
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Spondylolisthesis Spinal Fixation (MNH)
Date received	Dec 7, 1998
Decision date	Mar 30, 2000
Days to decision	479 days
Third-party review	No
Summary / Statement	Summary

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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