

K991031 COLORADO II SPINAL SYSTEMMay 10, 2000
408 days to decisionK991031 · Product code: **MNH** · Orthopedic
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Spondylolisthesis Spinal Fixation (MNH)
Date received	Mar 29, 1999
Decision date	May 10, 2000
Days to decision	408 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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