

K000425 ISOBAR SPINAL SYSTEMMar 7, 2000
27 days to decisionK000425 · Product code: **MNI** · Orthopedic
Source: <https://www.510kdatabase.net/k000425/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthosis, Spinal Pedicle Fixation (MNI)
Date received	Feb 9, 2000
Decision date	Mar 7, 2000
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Encore Orthopedics, Inc.
Location	Red Rock, TX, US
Contact	DEBBIE DE LOS SANTOS
510(k) history	85 submissions · 74 cleared · 1993-2004

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