

K013440 ISOBAR SPINAL SYSTEMNov 16, 2001
30 days to decisionK013440 · Product code: **MNI** · Orthopedic
Source: <https://www.510kdatabase.net/k013440/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthosis, Spinal Pedicle Fixation (MNI)
Date received	Oct 17, 2001
Decision date	Nov 16, 2001
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Scienc&apos;Tx USA, Inc.
Location	Austin, TX, US
Contact	JOANNA DROEGE
510(k) history	8 submissions · 8 cleared · 1999-2002

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