

K011807 SCS CLARIS SPINAL SCREWS, TYPES V,G,EAug 7, 2001
57 days to decisionK011807 · Product code: **MNI** · Orthopedic
Source: <https://www.510kdatabase.net/k011807/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthosis, Spinal Pedicle Fixation (MNI)
Date received	Jun 11, 2001
Decision date	Aug 7, 2001
Days to decision	57 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ortho Tec, LLC
Location	Pleasant Hill, CA, US
Contact	KAREN E WARDEN
510(k) history	22 submissions · 22 cleared · 1999-2004

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