

K130958 TRUE SPINAL FIXATION SYSTEMOct 17, 2013
195 days to decisionK130958 · Product code: **MNI** · Orthopedic
Source: <https://www.510kdatabase.net/k130958/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Spinal Pedicle Fixation (MNI)
Date received	Apr 5, 2013
Decision date	Oct 17, 2013
Days to decision	195 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Innovative Surgical Designs
Location	Bloomington, IN, US
Contact	ED MORRIS
510(k) history	2 submissions · 2 cleared · 2013-2014

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