

K161151 Spinal fixation systemSep 21, 2016
149 days to decisionK161151 · Product code: **MNH** · Orthopedic
Source: <https://www.510kdatabase.net/k161151/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Spondylolisthesis Spinal Fixation (MNH)
Date received	Apr 25, 2016
Decision date	Sep 21, 2016
Days to decision	149 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Canwell Medical Co., Ltd.
Location	Jinhua, CN
Contact	CHEN HUI
510(k) history	3 submissions · 3 cleared · 2015-2025

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