

K111690 DEVINE SPINAL SYSTEMNov 22, 2011
159 days to decisionK111690 · Product code: **MNH** · Orthopedic
Source: <https://www.510kdatabase.net/k111690/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Spondylolisthesis Spinal Fixation (MNH)
Date received	Jun 16, 2011
Decision date	Nov 22, 2011
Days to decision	159 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Changzhou Orthmed Medical Instrument Co., Ltd.
Location	Shanghai, CN
Contact	Diana Hong
510(k) history	2 submissions · 2 cleared · 2010-2011

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k111690/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 18, 2026