

K134011 GENERAL SPINAL SYSTEMSep 3, 2014
247 days to decisionK134011 · Product code: **MNH** · Orthopedic
Source: <https://www.510kdatabase.net/k134011/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Orthosis, Spondylolisthesis Spinal Fixation (MNH) |
| Date received | Dec 30, 2013 |
| Decision date | Sep 3, 2014 |
| Days to decision | 247 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Changzhou Dean Medical Instrument Co, Ltd. |
| Location | Shanghai, CN |
| Contact | Diana Hong |
| 510(k) history | 2 submissions · 2 cleared · 2014-2014 |

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