

K150684 WASTON General Spinal SystemNov 18, 2015
246 days to decisionK150684 · Product code: **MNI** · Orthopedic
Source: <https://www.510kdatabase.net/k150684/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Orthosis, Spinal Pedicle Fixation (MNI) |
| Date received | Mar 17, 2015 |
| Decision date | Nov 18, 2015 |
| Days to decision | 246 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Changzhou Waston Medical Appliance Co., Ltd. |
| Location | Shanghai, CN |
| Contact | Jack Lu |
| 510(k) history | 5 submissions · 5 cleared · 2010-2023 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k150684/> 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 28, 2026