

K151592 Gemmed pedicle screw spinal systemSep 24, 2015
104 days to decisionK151592 · Product code: **MNI** · Orthopedic
Source: <https://www.510kdatabase.net/k151592/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Spinal Pedicle Fixation (MNI)
Date received	Jun 12, 2015
Decision date	Sep 24, 2015
Days to decision	104 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Suzhou Gemmed Medical Instrument Co., Ltd.
Location	Zhangjiagang City, CN
Contact	Xue Fang Zhou
510(k) history	1 submissions · 1 cleared · 2015-2015

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k151592/> 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 17, 2026