

**K063708 4S SPINAL SYSTEM**Apr 24, 2007  
132 days to decisionK063708 · Product code: **MNI** · Orthopedic  
Source: <https://www.510kdatabase.net/k063708/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Spinal Pedicle Fixation (MNI)
Date received	Dec 13, 2006
Decision date	Apr 24, 2007
Days to decision	132 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Taeyeon Medical Co., Ltd.</b>
Location	Incheon, KR
Contact	GIL WOON CHOI
510(k) history	3 submissions · 3 cleared · 2007-2022

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