

K042928 MODIFICATION TO GLOBAL SPINAL FIXATION SYSTEM

Feb 17, 2005
118 days to decision

K042928 · Product code: **MNH** · Orthopedic
Source: <https://www.510kdatabase.net/k042928/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthosis, Spondylolisthesis Spinal Fixation (MNH)
Date received	Oct 22, 2004
Decision date	Feb 17, 2005
Days to decision	118 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	U&I Corp.
Location	Uijungbu, Gyeonggi-Do, KR
Contact	BETTY LIM
510(k) history	12 submissions · 12 cleared · 2005-2014

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Device record: <https://www.510kdatabase.net/k042928/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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