

K112643 FOCUS MIS SYSTEMJan 4, 2012
114 days to decisionK112643 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k112643/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Sep 12, 2011
Decision date	Jan 4, 2012
Days to decision	114 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	L & K Biomed Co., Ltd.
Location	Yongin-Si, KR
Contact	HEE K JOO
Website	https://www.lkbiomed.com
510(k) history	54 submissions · 54 cleared · 2010-2026

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