

K223565 LnK Spinal Fixation System /OpenLoc-L Spinal Fixation System, AccelFix Spinal Fixation System.Dec 23, 2022
24 days to decisionK223565 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k223565/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Nov 29, 2022
Decision date	Dec 23, 2022
Days to decision	24 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k223565/> 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 13, 2026