

K222229 Advanced LumFix Spinal Fixation SystemMay 25, 2023
304 days to decisionK222229 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k222229/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Jul 25, 2022
Decision date	May 25, 2023
Days to decision	304 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	CG Bio Co., Ltd.
Location	Seoul, KR
Contact	Iris Kim
510(k) history	5 submissions · 5 cleared · 2013-2026

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