

K250582 COLONNADE Posterior Screw Fixation SystemMay 8, 2025
70 days to decisionK250582 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k250582/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Feb 27, 2025
Decision date	May 8, 2025
Days to decision	70 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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