

K240180 Orthopeasia Spinal Fixation SystemAug 30, 2024
220 days to decisionK240180 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k240180/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Jan 23, 2024
Decision date	Aug 30, 2024
Days to decision	220 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Orthopeasia Co., Ltd.
Location	Bangpla, Bangplee, Samutprakarn, TH
Contact	Phunyawee Ritshima
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	Aztech Regulatory & Quality, LLC
Contact	Joseph Azary

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k240180/> 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