

K243106 CarboClear® Hybrid Pedicle Screw SystemNov 5, 2024
36 days to decisionK243106 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k243106/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Sep 30, 2024
Decision date	Nov 5, 2024
Days to decision	36 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	CarboFix Orthopedics , Ltd.
Location	Herzliya, IL
Contact	Hila Wachsler-Avrahami
510(k) history	32 submissions · 32 cleared · 2011-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243106/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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