

K240846 CarboClear® Hybrid Pedicle Screw SystemApr 25, 2024
29 days to decisionK240846 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k240846/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Mar 27, 2024
Decision date	Apr 25, 2024
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	CarboClear® Hybrid Navigated Instruments; CarboClear® Hybrid Fenestrated Pedicle Screw System and High V+® Bone Cement; CarboClear® X Fenestrated Pedicle Screw System and High V+® Bone Cement

APPLICANT

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

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