

K210716 CarboClear X Pedicle Screw System, CarboClear X Navigated InstrumentsApr 6, 2021
27 days to decisionK210716 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k210716/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Mar 10, 2021
Decision date	Apr 6, 2021
Days to decision	27 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

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