

K231280 CarboClear® X Pedicle Screw SystemJul 3, 2023
61 days to decisionK231280 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k231280/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	May 3, 2023
Decision date	Jul 3, 2023
Days to decision	61 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	CarboClear® X Navigated Instruments; CarboClear® X Fenestrated Pedicle Screw System with High V+® Bone Cement

APPLICANT

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

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