

**K200519 CarboClear® II Pedicle Screw System**Apr 30, 2020  
59 days to decisionK200519 · Product code: **NKB** · Orthopedic  
Source: <https://www.510kdatabase.net/k200519/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Mar 2, 2020
Decision date	Apr 30, 2020
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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