

**K182377 CarboClear® Pedicle Screw System**Sep 27, 2018  
27 days to decisionK182377 · Product code: **NKB** · Orthopedic  
Source: <https://www.510kdatabase.net/k182377/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Aug 31, 2018
Decision date	Sep 27, 2018
Days to decision	27 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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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k182377/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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