

**K232341 CarboClear® Pedicle Screw System**Oct 10, 2023  
67 days to decisionK232341 · Product code: **NKB** · Orthopedic  
Source: <https://www.510kdatabase.net/k232341/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Aug 4, 2023
Decision date	Oct 10, 2023
Days to decision	67 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

**CLINICAL EVIDENCE - NCT02626624****Safety and Efficacy of the CarboClear Pedicle Screw System**

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Status	Completed
Enrollment	57 patients (actual)
Study sites	8 sites
Condition studied	Degenerative Disc Disease; Spondylolisthesis, Grade 1
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Dec 28, 2022
Sponsor	CarboFix Orthopedics Ltd. (Industry)

**Primary outcome**

Fusion: Evaluated Radiographically (by AP, Lateral and Flexion/Extension X-Rays) by Independent Radiographic Core Lab.

**Secondary outcome**

Subject's Overall Well-Being: Assessed by 12-Item Short Form Health Survey (SF-12) Patient Questionnaire

Source: ClinicalTrials.gov / U.S. National Library of Medicine - [clinicaltrials.gov/study/NCT02626624](https://clinicaltrials.gov/study/NCT02626624)