

**K201926 CarboClear® Pedicle Screw System, CarboClear® II
Pedicle Screw System**Aug 7, 2020
28 days to decisionK201926 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k201926/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Thoracolumbosacral Pedicle Screw System (NKB) |
| Date received | Jul 10, 2020 |
| Decision date | Aug 7, 2020 |
| Days to decision | 28 days |
| Third-party review | 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 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k201926/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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