

**K254045 CarboClear® Posterior Cervical Screw System**Mar 16, 2026  
89 days to decisionK254045 · Product code: **NKG** · Orthopedic  
Source: <https://www.510kdatabase.net/k254045/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                 |
| Submission type       | Traditional  |
| Device classification | Posterior Cervical Screw System (NKG)              |
| Date received         | Dec 17, 2025                                       |
| Decision date         | Mar 16, 2026                                       |
| Days to decision      | 89 days  |
| Third-party review    | No   |
| Combination product   | No   |
| PCCP authorized       | No   |
| Summary / Statement   | Summary  |
| Other names           | CarboClear® Hybrid Posterior Cervical Screw System |

**APPLICANT**

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

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