

K151010 Piccolo Composite Nailing SystemJul 28, 2015
104 days to decisionK151010 · Product code: **HSB** · Orthopedic
Source: <https://www.510kdatabase.net/k151010/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Rod, Fixation, Intramedullary And Accessories (HSB) |
| Date received | Apr 15, 2015 |
| Decision date | Jul 28, 2015 |
| Days to decision | 104 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | CarboFix Orthopedics , Ltd. |
| Location | Herzliya, IL |
| Contact | YAEL RUBIN |
| 510(k) history | 32 submissions · 32 cleared · 2011-2026 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k151010/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026