

K233482 Equinoxe® Central Screw Baseplate SystemJul 18, 2024
266 days to decisionK233482 · Product code: **PHX** · Orthopedic
Source: <https://www.510kdatabase.net/k233482/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Shoulder Prosthesis, Reverse Configuration (PHX) |
| Date received | Oct 26, 2023 |
| Decision date | Jul 18, 2024 |
| Days to decision | 266 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Exactech, Inc. |
| Location | Gainesville, FL, US |
| Contact | Liz Howell |
| 510(k) history | 186 submissions · 174 cleared · 1986-2026 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k233482/> 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