

K212356 Exactech® Equinoxe® Laser Cage GlenoidMar 4, 2022
218 days to decisionK212356 · Product code: **KWS** · Orthopedic
Source: <https://www.510kdatabase.net/k212356/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Prosthesis, Shoulder, Semi-constrained, Metal/polymer Cemented (KWS) |
| Date received | Jul 29, 2021 |
| Decision date | Mar 4, 2022 |
| Days to decision | 218 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212356/> 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 13, 2026