

**K063414 MODIFICATION TO: FMP METAL/METAL
ACETABULAR INSERT, MODELS 499-28, 499-34, 499-38**Dec 12, 2006
29 days to decisionK063414 · Product code: **KWA** · Orthopedic
Source: <https://www.510kdatabase.net/k063414/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Prosthesis, Hip, Semi-constrained (metal Uncemented Acetabular Component) (KWA) |
| Date received | Nov 13, 2006 |
| Decision date | Dec 12, 2006 |
| Days to decision | 29 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Encore Medical, L.P. |
| Location | Austin, TX, US |
| Contact | TEFFANY HUTTO |
| 510(k) history | 81 submissions · 81 cleared · 2002-2026 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k063414/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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