

K003250 FMP METAL/METAL ACETABULAR INSERTJan 25, 2001
100 days to decisionK003250 · Product code: **KWA** · Orthopedic
Source: <https://www.510kdatabase.net/k003250/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained (metal Uncemented Acetabular Component) (KWA)
Date received	Oct 17, 2000
Decision date	Jan 25, 2001
Days to decision	100 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Encore Orthopedics, Inc.
Location	Red Rock, TX, US
Contact	DEBBIE DE LOS SANTOS
510(k) history	85 submissions · 74 cleared · 1993-2004

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k003250/> 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 20, 2026