

K121544 DYNASTY BIOFOAM SHELLJul 30, 2012
66 days to decisionK121544 · Product code: **KWA** · Orthopedic
Source: <https://www.510kdatabase.net/k121544/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained (metal Uncemented Acetabular Component) (KWA)
Date received	May 25, 2012
Decision date	Jul 30, 2012
Days to decision	66 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Wrightmedicaltechnologyinc
Location	Arlington, TN, US
Contact	YUAN LI
510(k) history	302 submissions · 291 cleared · 1993-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k121544/> 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 18, 2026