

K982389 ODC B2 BIPOLAR CUPOct 7, 1998
90 days to decisionK982389 · Product code: **KWY** · Orthopedic
Source: <https://www.510kdatabase.net/k982389/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Hemi-, Femoral, Metal/polymer, Cemented Or Uncemented (KWY)
Date received	Jul 9, 1998
Decision date	Oct 7, 1998
Days to decision	90 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Ortho Development Corp.
Location	Draper, UT, US
Contact	CAROL FREASIER
510(k) history	45 submissions · 43 cleared · 1996-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k982389/> 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 21, 2026