

K915868 PERFECTA TOTAL HIP SYSTEM, HEMI-HEAD COMPONENT

Mar 23, 1992
84 days to decision

K915868 · Product code: **KWL** · Orthopedic
Source: <https://www.510kdatabase.net/k915868/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Hemi-, Femoral, Metal (KWL)
Date received	Dec 30, 1991
Decision date	Mar 23, 1992
Days to decision	84 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Orthomet, Inc.
Location	Plymouth, MN, US
Contact	DENNIS H CRANE
510(k) history	60 submissions · 41 cleared · 1986-1995

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k915868/> 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