

**K973614 FOUNDATION UNIPOLAR FEMORAL HEAD WITH
MODULAR NECK LENGTH SLEEVES**Dec 18, 1997
86 days to decisionK973614 · Product code: **KWL** · Orthopedic
Source: <https://www.510kdatabase.net/k973614/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Hemi-, Femoral, Metal (KWL)
Date received	Sep 23, 1997
Decision date	Dec 18, 1997
Days to decision	86 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/k973614/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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