

**K162957 U2 Femoral Head**Jul 17, 2017  
266 days to decisionK162957 · Product code: **LPH** · Orthopedic  
Source: <https://www.510kdatabase.net/k162957/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Metal/polymer, Porous Uncemented (LPH)
Date received	Oct 24, 2016
Decision date	Jul 17, 2017
Days to decision	266 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>United Orthopedic Corporation</b>
Location	Hsinchu, TW
Contact	GIMPEL CHIEN
510(k) history	40 submissions · 40 cleared · 2011-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k162957/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 16, 2026