

**K152439 U2 Bipolar Implant and 22mm Femoral Head**Apr 7, 2016  
224 days to decisionK152439 · Product code: **KWY** · Orthopedic  
Source: <https://www.510kdatabase.net/k152439/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Hemi-, Femoral, Metal/polymer, Cemented Or Uncemented (KWY)
Date received	Aug 27, 2015
Decision date	Apr 7, 2016
Days to decision	224 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>United Orthopedic Corporation</b>
Location	Hsinchu, TW
Contact	Karen Ho
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/k152439/> 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 17, 2026