

K221675 United U2 femoral head, 22mm delta ceramic headNov 4, 2022
148 days to decisionK221675 · Product code: **LPH** · Orthopedic
Source: <https://www.510kdatabase.net/k221675/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Hip, Semi-constrained, Metal/polymer, Porous Uncemented (LPH)
Date received	Jun 9, 2022
Decision date	Nov 4, 2022
Days to decision	148 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	United Orthopedic Corporation
Location	Hsinchu, TW
Contact	Lois Ho
510(k) history	40 submissions · 40 cleared · 2011-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k221675/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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