

K221705 U2 Total Knee System-PF+Feb 28, 2023
260 days to decisionK221705 · Product code: **MBH** · Orthopedic
Source: <https://www.510kdatabase.net/k221705/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patello/femorotibial, Semi-constrained, Uncemented, Porous, Coated, Polymer/metal/polymer (MBH)
Date received	Jun 13, 2022
Decision date	Feb 28, 2023
Days to decision	260 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/k221705/> 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 14, 2026