

**K161705 U2 Total Knee System E-XPE products**Mar 16, 2017  
269 days to decisionK161705 · Product code: **JWH** · Orthopedic  
Source: <https://www.510kdatabase.net/k161705/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Jun 20, 2016
Decision date	Mar 16, 2017
Days to decision	269 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161705/> 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