

K150829 U2 Total Knee System- Additional SizesSep 25, 2015
179 days to decisionK150829 · Product code: **JWH** · Orthopedic
Source: <https://www.510kdatabase.net/k150829/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH) |
| Date received | Mar 30, 2015 |
| Decision date | Sep 25, 2015 |
| Days to decision | 179 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k150829/> 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 17, 2026