

K131116 U2 TOTAL KNEE SYSTEM - PSA TYPE, OFFSET STEM ADAPTEROct 30, 2013
191 days to decisionK131116 · Product code: **JWH** · Orthopedic
Source: <https://www.510kdatabase.net/k131116/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Apr 22, 2013
Decision date	Oct 30, 2013
Days to decision	191 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

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