

**K161360 U2 Total Knee System, PSA Tibial Insert**Feb 1, 2017  
261 days to decisionK161360 · Product code: **JWH** · Orthopedic  
Source: <https://www.510kdatabase.net/k161360/>**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	May 16, 2016
Decision date	Feb 1, 2017
Days to decision	261 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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