

K210961 U2 Total Knee System, XPE Tibial Insert, PS PLUS

Apr 21, 2021
21 days to decision

K210961 · Product code: **JWH** · Orthopedic
Source: <https://www.510kdatabase.net/k210961/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Mar 31, 2021
Decision date	Apr 21, 2021
Days to decision	21 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
