

K243656 U2 Total Knee System – PF+ PatellaJul 31, 2025
247 days to decisionK243656 · Product code: **MBH** · Orthopedic
Source: <https://www.510kdatabase.net/k243656/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patello/femorotibial, Semi-constrained, Uncemented, Porous, Coated, Polymer/metal/polymer (MBH)
Date received	Nov 26, 2024
Decision date	Jul 31, 2025
Days to decision	247 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	USTAR II System– PF+ Patella

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	NJK & Associates, Inc.
Contact	Natalie J Kennel

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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