

K240327 UNIKO PointCloud™ Knee InstrumentsJun 27, 2024
146 days to decisionK240327 · Product code: **JWH** · Orthopedic
Source: <https://www.510kdatabase.net/k240327/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Feb 2, 2024
Decision date	Jun 27, 2024
Days to decision	146 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Unik Orthopedics, Inc.
Location	San Jose, CA, US
Contact	Charlie Chi
510(k) history	2 submissions · 2 cleared · 2020-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k240327/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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