

K213673 b-ONE MOBIO Total Knee SystemJan 21, 2022
60 days to decisionK213673 · Product code: **JWH** · Orthopedic
Source: <https://www.510kdatabase.net/k213673/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Nov 22, 2021
Decision date	Jan 21, 2022
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	B-One Ortho, Corp.
Location	Cedar Knolls, NJ, US
Contact	Allison Gecik
510(k) history	12 submissions · 12 cleared · 2018-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213673/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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