

**K222431 b-ONER MOBIO Total Knee System**Oct 6, 2022  
56 days to decisionK222431 · Product code: **JWH** · Orthopedic  
Source: <https://www.510kdatabase.net/k222431/>**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	Aug 11, 2022
Decision date	Oct 6, 2022
Days to decision	56 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k222431/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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