

K180446 b-ONE Total Knee SystemOct 12, 2018
234 days to decisionK180446 · Product code: **JWH** · Orthopedic
Source: <https://www.510kdatabase.net/k180446/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Feb 20, 2018
Decision date	Oct 12, 2018
Days to decision	234 days
Third-party review	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

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