

K183025 MOBIO Total Knee System Posterior Stabilized (PS and PS+) Tibial Inserts, MOBIO Total Knee System Patellar Component

Jan 28, 2019
88 days to decision

K183025 · Product code: **JWH** · Orthopedic
Source: <https://www.510kdatabase.net/k183025/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Nov 1, 2018
Decision date	Jan 28, 2019
Days to decision	88 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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k183025/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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