

**K244039 MedalOne Total Knee System**Feb 28, 2025  
60 days to decisionK244039 · Product code: **JWH** · Orthopedic  
Source: <https://www.510kdatabase.net/k244039/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Dec 30, 2024
Decision date	Feb 28, 2025
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Suzhou Microport Orthorecon Co., Ltd.</b>
Location	Suzhou, CN
Contact	Qingling Bao
510(k) history	1 submissions · 1 cleared · 2025-2025

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k244039/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026