

K231947 EVOLUTION® Cement KeelOct 31, 2023
123 days to decisionK231947 · Product code: **JWH** · Orthopedic
Source: <https://www.510kdatabase.net/k231947/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Jun 30, 2023
Decision date	Oct 31, 2023
Days to decision	123 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Microport Orthopedics, Inc.
Location	Arlington, TN, US
Contact	Jonas Susaraba
510(k) history	37 submissions · 37 cleared · 2014-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231947/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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