

K240043 EVOLUTION® Hinge Knee SystemApr 1, 2024
87 days to decisionK240043 · Product code: **KRO** · Orthopedic
Source: <https://www.510kdatabase.net/k240043/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Femorotibial, Constrained, Cemented, Metal/polymer (KRO)
Date received	Jan 5, 2024
Decision date	Apr 1, 2024
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	GUARDIAN™ limb Salvage System;DCW Modular Distal Femoral System;REPIPHYSIS™ Limb Salvage System;EVOLUTION® MP Total Knee System; EVOLUTION® MP Total Knee System; EVOLUTION® MP Adaptive CS Insert; EVOLUTION® MP Adaptive PS Tibial Insert; EVOLUTION® MP CS/CR Porous Femur/EVOLUTION® Adaptive CS and PS Inserts; EVOLUTION® Revision CCK System; ADVANCE® Double High Insert; ADVANCE® A-CLASS® Tibial Insert; ADVANCE® Knee System; ADVANCE® Ultra-Congruent Tibial Inse

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k240043/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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