

**K180317 EVOLUTION® Knee Systems – MR Labeling,
EVOLUTION® BIOFOAM® Tibial System, EVOLUTION®
Revision Tibial System, EVOLUTION® Revision CCK System**May 4, 2018
88 days to decisionK180317 · Product code: **MBH** · Orthopedic
Source: <https://www.510kdatabase.net/k180317/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patello/femorotibial, Semi-constrained, Uncemented, Porous, Coated, Polymer/metal/polymer (MBH)
Date received	Feb 5, 2018
Decision date	May 4, 2018
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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