

**K170288 BIOFOAM® Additive Manufacturing (BIOFOAM® AM),
ADVANCE® BIOFOAM® Tibial Base, EVOLUTION® BIOFOAM®
Tibial Base, DYNASTY® BIOFOAM® Acetabular Shell**Jun 15, 2017
136 days to decisionK170288 · Product code: **MBH** · Orthopedic
Source: <https://www.510kdatabase.net/k170288/>**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	Jan 30, 2017
Decision date	Jun 15, 2017
Days to decision	136 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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