

K201157 Prime BIOFOAM® Multi-Hole ShellsAug 24, 2021
481 days to decisionK201157 · Product code: **MBL** · Orthopedic
Source: <https://www.510kdatabase.net/k201157/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Uncemented, Metal/polymer, Porous (MBL)
Date received	Apr 30, 2020
Decision date	Aug 24, 2021
Days to decision	481 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k201157/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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