

K152298 EVOLUTION BIOFOAM Tibial Base, EVOLUTION Modular Keels, ADVANCE Modular Keels, ADVANCE Bullet-Tipped Keels, ADVANCE BIOFOAM Tibial Base

Nov 16, 2015
95 days to decision

K152298 · Product code: **MBH** · Orthopedic
Source: <https://www.510kdatabase.net/k152298/>

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	Aug 13, 2015
Decision date	Nov 16, 2015
Days to decision	95 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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