

K191084 The Optimotion Blue Total Knee SystemApr 7, 2020
349 days to decisionK191084 · Product code: **MBH** · Orthopedic
Source: <https://www.510kdatabase.net/k191084/>**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	Apr 24, 2019
Decision date	Apr 7, 2020
Days to decision	349 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Optimotion Implants, LLC
Location	Winter Park, FL, US
Contact	Dan Justin
510(k) history	3 submissions · 3 cleared · 2020-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191084/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026