

K191966 NewPrim SystemFeb 13, 2020
205 days to decisionK191966 · Product code: **KWH** · Orthopedic
Source: <https://www.510kdatabase.net/k191966/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Toe, Constrained, Polymer (KWH)
Date received	Jul 23, 2019
Decision date	Feb 13, 2020
Days to decision	205 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Brm Extremities
Location	Milano, MI, US
Contact	Andrea De Maglio
510(k) history	2 submissions · 2 cleared · 2020-2022

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