

K201611 Apex Knee SystemApr 2, 2021
291 days to decisionK201611 · Product code: **JWH** · Orthopedic
Source: <https://www.510kdatabase.net/k201611/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Jun 15, 2020
Decision date	Apr 2, 2021
Days to decision	291 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Omnilife Science
Location	Raynham, MA, US
Contact	Dipti Dharia
510(k) history	7 submissions · 7 cleared · 2007-2021

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k201611/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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