

K190122 Renovis A200 PS Knee System as part of the Renovis A200 Knee SystemJun 20, 2019
146 days to decisionK190122 · Product code: **JWH** · Orthopedic
Source: <https://www.510kdatabase.net/k190122/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Jan 25, 2019
Decision date	Jun 20, 2019
Days to decision	146 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Renovis Surgical Technologies
Location	Redlands, CA, US
Contact	Anthony Debenedictis
510(k) history	7 submissions · 7 cleared · 2015-2019

REGULATORY CONSULTANT

Consulting firm	MEDlcept, Inc.
Contact	Sharyn Orton

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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