

K190439 Engage™ Partial Knee SystemNov 21, 2019
269 days to decisionK190439 · Product code: **NJD** · Orthopedic
Source: <https://www.510kdatabase.net/k190439/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Femorotibial, Unicompartmental/unicondylar, Uncemented, Porous-coated, Metal/polymer (NJD)
Date received	Feb 25, 2019
Decision date	Nov 21, 2019
Days to decision	269 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Engage Uni, LLC
Location	Winter Park, FL, US
Contact	Nicholas Slater
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	Engage Surgical
Contact	Nicholas Slater

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k190439/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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