

K191192 SurgTech GENOLL Total Knee SystemAug 1, 2019
90 days to decisionK191192 · Product code: **JWH** · Orthopedic
Source: <https://www.510kdatabase.net/k191192/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	May 3, 2019
Decision date	Aug 1, 2019
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Surgtech, Inc.
Location	Westlake, OH, US
Contact	Xuegong Yu
510(k) history	6 submissions · 6 cleared · 2016-2019

REGULATORY CONSULTANT

Consulting firm	Orchid Design
Contact	Kellen Hills

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/k191192/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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