

K200765 Genius / Genuin Total Knee SystemMay 5, 2021
407 days to decisionK200765 · Product code: **JWH** · Orthopedic
Source: <https://www.510kdatabase.net/k200765/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Mar 24, 2020
Decision date	May 5, 2021
Days to decision	407 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Biorad Medisys Pvt, Ltd.
Location	Pune, IN
Contact	Sudhakar Saxena
510(k) history	1 submissions · 1 cleared · 2021-2021

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