

K211664 GMK Sphere RevisionJul 29, 2021
58 days to decisionK211664 · Product code: **JWH** · Orthopedic
Source: <https://www.510kdatabase.net/k211664/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Jun 1, 2021
Decision date	Jul 29, 2021
Days to decision	58 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medacta International S.A.
Location	Castel San Pietro, CH
Contact	Stefano Baj
Website	https://www.medacta.com
510(k) history	164 submissions · 164 cleared · 2008-2026

REGULATORY CONSULTANT

Consulting firm	Medacta USA
Contact	Chris Lussier

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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