

K140826 GMK SPHERE EXTENSIONJul 15, 2014
105 days to decisionK140826 · Product code: **JWH** · Orthopedic
Source: <https://www.510kdatabase.net/k140826/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Apr 1, 2014
Decision date	Jul 15, 2014
Days to decision	105 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medacta International
Location	San Diego, CA, US
Contact	ADAM GROSS
510(k) history	39 submissions · 39 cleared · 2011-2016

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