

**K181635 GMK Sphere CR Tibial Inserts**Aug 23, 2018  
63 days to decisionK181635 · Product code: **JWH** · Orthopedic  
Source: <https://www.510kdatabase.net/k181635/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Jun 21, 2018
Decision date	Aug 23, 2018
Days to decision	63 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k181635/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 16, 2026