

K172347 GMK Hinge, GMK RevisionNov 1, 2017
90 days to decisionK172347 · Product code: **KRO** · Orthopedic
Source: <https://www.510kdatabase.net/k172347/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Prosthesis, Knee, Femorotibial, Constrained, Cemented, Metal/polymer (KRO) |
| Date received | Aug 3, 2017 |
| Decision date | Nov 1, 2017 |
| Days to decision | 90 days |
| Third-party review | 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 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k172347/> Data sourced from FDA 510(k) public records (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. - Generated May 16, 2026