

K163311 GMK Revision Femoral Distal AugmentationDec 21, 2016
28 days to decisionK163311 · Product code: **KRO** · Orthopedic
Source: <https://www.510kdatabase.net/k163311/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Knee, Femorotibial, Constrained, Cemented, Metal/polymer (KRO)
Date received	Nov 23, 2016
Decision date	Dec 21, 2016
Days to decision	28 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

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