

**K161741 GMK UNI**Apr 14, 2017  
294 days to decisionK161741 · Product code: **HSX** · Orthopedic  
Source: <https://www.510kdatabase.net/k161741/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Femorotibial, Non-constrained, Cemented, Metal/polymer (HSX)
Date received	Jun 24, 2016
Decision date	Apr 14, 2017
Days to decision	294 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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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

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