

**K191016 COPAL exchange G Hip and Knee Spacers**Nov 1, 2019  
198 days to decisionK191016 · Product code: **KWY** · Orthopedic  
Source: <https://www.510kdatabase.net/k191016/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Hemi-, Femoral, Metal/polymer, Cemented Or Uncemented (KWY)
Date received	Apr 17, 2019
Decision date	Nov 1, 2019
Days to decision	198 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Heraeus Medical GmbH</b>
Location	Wehrheim, DE
Contact	Ljuba Jitaau
510(k) history	13 submissions · 13 cleared · 2014-2024

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