

K234028 COPAL® exchange G hip spacerFeb 15, 2024
57 days to decisionK234028 · Product code: **KWL** · Orthopedic
Source: <https://www.510kdatabase.net/k234028/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Hemi-, Femoral, Metal (KWL)
Date received	Dec 20, 2023
Decision date	Feb 15, 2024
Days to decision	57 days
Third-party review	No
PCCP authorized	No
Summary / Statement	Summary
Other names	COPAL® G+V

APPLICANT

Company	Heraeus Medical GmbH
Location	Wehrheim, DE
Contact	Heike Gustke
510(k) history	13 submissions · 13 cleared · 2014-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k234028/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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