

K222570 COPAL knee mouldsFeb 4, 2023
165 days to decisionK222570 · Product code: **JWH** · Orthopedic
Source: <https://www.510kdatabase.net/k222570/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Aug 23, 2022
Decision date	Feb 4, 2023
Days to decision	165 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k222570/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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