

K231526 CORAIL Cemented Femoral StemDec 19, 2023
207 days to decisionK231526 · Product code: **KWY** · Orthopedic
Source: <https://www.510kdatabase.net/k231526/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Hemi-, Femoral, Metal/polymer, Cemented Or Uncemented (KWY)
Date received	May 26, 2023
Decision date	Dec 19, 2023
Days to decision	207 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Depuy Ireland UC
Location	Ringaskiddy, IE
Contact	Amy Joyce
510(k) history	47 submissions · 47 cleared · 2018-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231526/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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