

K260536 Prostalac Hip System, SmartSet V+G Dual Antibiotic Bone CementMay 15, 2026
87 days to decisionK260536 · Product code: **KWL** · Orthopedic
Source: <https://www.510kdatabase.net/k260536/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Hemi-, Femoral, Metal (KWL)
Date received	Feb 17, 2026
Decision date	May 15, 2026
Days to decision	87 days
Third-party review	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Depuy Ireland UC
Location	Ringaskiddy, IE
Contact	Megan Palumbo
510(k) history	48 submissions · 48 cleared · 2018-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k260536/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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