

K251292 RECLAIM Monobloc Revision Femoral StemMay 23, 2025
28 days to decisionK251292 · Product code: **LZO** · Orthopedic
Source: <https://www.510kdatabase.net/k251292/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Hip, Semi-constrained, Metal/ceramic/polymer, Cemented Or Non-porous, Uncemented (LZO)
Date received	Apr 25, 2025
Decision date	May 23, 2025
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251292/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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