

K221462 DePuy Reclaim Monobloc Revision Femoral StemOct 21, 2022
155 days to decisionK221462 · Product code: **LZO** · Orthopedic
Source: <https://www.510kdatabase.net/k221462/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Metal/ceramic/polymer, Cemented Or Non-porous, Uncemented (LZO)
Date received	May 19, 2022
Decision date	Oct 21, 2022
Days to decision	155 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k221462/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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