

K211657 EMPHASYS Femoral StemsAug 5, 2021
69 days to decisionK211657 · Product code: **LZO** · Orthopedic
Source: <https://www.510kdatabase.net/k211657/>**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 28, 2021
Decision date	Aug 5, 2021
Days to decision	69 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Depuy Synthes, Irenc.
Contact	Clare Hill

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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