

K213839 DePuy Corail AMT Hip ProsthesisJan 6, 2022
28 days to decisionK213839 · Product code: **LZO** · Orthopedic
Source: <https://www.510kdatabase.net/k213839/>**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	Dec 9, 2021
Decision date	Jan 6, 2022
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	DePuy Orthopaedics, Inc.
Location	Warsaw, IN, US
Contact	Erin Combs
510(k) history	206 submissions · 204 cleared · 1998-2023

REGULATORY CONSULTANT

Consulting firm	Depuy(Ireland)
Contact	Paul Shin

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

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