

**K231873 DePuy SUMMIT Porocoat Hip Prosthesis – MR
Conditional, DePuy SUMMIT DuoFix Hip Prosthesis – MR
Conditional, DePuy SUMMIT Cemented Hip Prosthesis – MR
Conditional, DePuy SUMMIT FX Cemented Hip Prosthesis – MR
Conditional, DePuy SUMMIT Basic Press-Fit Hip Prosthesis –
MR Conditional**

Jan 19, 2024
207 days to decision

K231873 · Product code: MEH · Orthopedic
Source: <https://www.510kdatabase.net/k231873/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Uncemented, Metal / Polymer, Non-porous, Calcium Phosphate (MEH)
Date received	Jun 26, 2023
Decision date	Jan 19, 2024
Days to decision	207 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

REGULATORY CONSULTANT

Consulting firm	DePuy Synthes
Contact	Jennifer Hill

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k231873/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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