

K210581 Actis DuoFix Hip Prosthesis- CollarlessMay 20, 2021
83 days to decisionK210581 · Product code: **MEH** · Orthopedic
Source: <https://www.510kdatabase.net/k210581/>**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	Feb 26, 2021
Decision date	May 20, 2021
Days to decision	83 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	DePuy Orthopaedics, Inc.
Contact	Erin Combs

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.netDevice record: <https://www.510kdatabase.net/k210581/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026