

K193398 Summit DuoFix HA CoatingFeb 4, 2020
60 days to decisionK193398 · Product code: **MEH** · Orthopedic
Source: <https://www.510kdatabase.net/k193398/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Hip, Semi-constrained, Uncemented, Metal / Polymer, Non-porous, Calcium Phosphate (MEH)
Date received	Dec 6, 2019
Decision date	Feb 4, 2020
Days to decision	60 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	Margaret Shaughnessy

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k193398/> 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 26, 2026