

K201348 DePuy 3D Additive TriFlange Acetabular CupJun 16, 2022
756 days to decisionK201348 · Product code: **LPH** · Orthopedic
Source: <https://www.510kdatabase.net/k201348/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Metal/polymer, Porous Uncemented (LPH)
Date received	May 21, 2020
Decision date	Jun 16, 2022
Days to decision	756 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Depuy International, Ltd.
Location	Leeds, GB
Contact	Erin Combs
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	DePuy Orthopaedics, Inc.
Contact	Reily Inman

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/k201348/> 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