FDA 510(k) Premarket Notification

CLEARED

K201348 DePuy 3D Additive TriFlange Acetabular Cup

Jun 16, 2022
756 days to decision

K201348 · 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