FDA 510(k) Premarket Notification

K202472 ACTIS Duofix Hip Prosthesis

CLEARED

Oct 21, 2020
54 days to decision

K202472 · Product code: **LPH** · Orthopedic
Source: https://www.510kdatabase.net/k202472/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Hip, Semi-constrained, Metal/polymer, Porous Uncemented (LPH)
Date received	Aug 28, 2020
Decision date	Oct 21, 2020
Days to decision	54 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**DePuy Orthopaedics, Inc.**
Location	Warsaw, IN, US
Contact	Karen Mahoney
510(k) history	206 submissions · 204 cleared · 1998-2023

REGULATORY CONSULTANT

Consulting firm	**Depuy Ireland**
Contact	Ann Geraghty

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