FDA 510(k) Premarket Notification

CLEARED

K203694 DELTA XTEND Reverse Shoulder System

Jul 22, 2021
216 days to decision

K203694 · Product code: **PHX** · Orthopedic
Source: https://www.510kdatabase.net/k203694/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shoulder Prosthesis, Reverse Configuration (PHX)
Date received	Dec 18, 2020
Decision date	Jul 22, 2021
Days to decision	216 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	**DePuy Orthopaedics, Inc.**
Contact	Jaclyn Cincotta

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