FDA 510(k) Premarket Notification

K192855 DELTA XTEND(TM) Reverse Shoulder System

CLEARED

Feb 24, 2020
143 days to decision

K192855 · Product code: **PHX** · Orthopedic
Source: https://www.510kdatabase.net/k192855/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shoulder Prosthesis, Reverse Configuration (PHX)
Date received	Oct 4, 2019
Decision date	Feb 24, 2020
Days to decision	143 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Depuy(Ireland)**
Location	Cork, IE
Contact	Ashley Goncalo
510(k) history	13 submissions · 13 cleared · 2010-2022

REGULATORY CONSULTANT

Consulting firm	**DePuy Orthopaedics, Inc.**
Contact	Ashley Goncalo

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