

**K203694 DELTA XTEND Reverse Shoulder System**Jul 22, 2021  
216 days to decisionK203694 · Product code: **PHX** · Orthopedic  
Source: <https://www.510kdatabase.net/k203694/>**SUBMISSION DETAILS**

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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**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>DePuy Orthopaedics, Inc.</b>
Contact	Jaclyn Cincotta

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

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