

**K212710 GLOBAL UNITE™ Platform Shoulder System**Sep 15, 2021  
20 days to decisionK212710 · Product code: **PHX** · Orthopedic  
Source: <https://www.510kdatabase.net/k212710/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Shoulder Prosthesis, Reverse Configuration (PHX)
Date received	Aug 26, 2021
Decision date	Sep 15, 2021
Days to decision	20 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	Yayoi Fujimaki
510(k) history	47 submissions · 47 cleared · 2018-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>DePuy Mitek, Inc.</b>
Contact	Yayoi Fujimaki

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212710/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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