

**K241000 ATTUNE™ Revision Knee System**Jul 11, 2024  
90 days to decisionK241000 · Product code: **JWH** · Orthopedic  
Source: <https://www.510kdatabase.net/k241000/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Apr 12, 2024
Decision date	Jul 11, 2024
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	DePuy Knee Prosthesis System Universal Stem Extensions and Universal Femoral Metaphyseal Sleeves; DePuy Sigma PS Femoral Components; DePuy Sigma Cruciate Retaining (C/R) Porocoat Femoral Components; S-ROM™ NOILES™ Rotating Hinge Knee System; DePuy P.F.C.™ SIGMA™ Total Knee System; DePuy SIGMA™ Total Knee System;

**APPLICANT**

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

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