

K253197 ATTUNE™ Total Knee SystemNov 19, 2025
54 days to decisionK253197 · Product code: **JWH** · Orthopedic
Source: <https://www.510kdatabase.net/k253197/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Sep 26, 2025
Decision date	Nov 19, 2025
Days to decision	54 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	ATTUNE™ Revision Sleeve LPS™ Femoral Adaptors

APPLICANT

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

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