

K213781 ATTUNE® Porous Fixed Bearing Tibial Base with AFFIXIUM™ 3DPJan 18, 2022
46 days to decisionK213781 · Product code: MBH · Orthopedic
Source: <https://www.510kdatabase.net/k213781/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Knee, Patello/femorotibial, Semi-constrained, Uncemented, Porous, Coated, Polymer/metal/polymer (MBH)
Date received	Dec 3, 2021
Decision date	Jan 18, 2022
Days to decision	46 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	DePuy Orthopaedics, Inc.
Contact	Hannah Foley

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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