

K251975 Achieve Partial Knee System - Porous Coated CoCrMo Femoral Component

Sep 2, 2025
68 days to decision

K251975 · Product code: **NJD** · Orthopedic
Source: <https://www.510kdatabase.net/k251975/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Femorotibial, Unicompartmental/unicondylar, Uncemented, Porous-coated, Metal/polymer (NJD)
Date received	Jun 26, 2025
Decision date	Sep 2, 2025
Days to decision	68 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ignite Orthomotion
Location	Winona Lake, IN, US
Contact	Russell Parrott
510(k) history	2 submissions · 2 cleared · 2024-2025

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k251975/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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