

K242307 ACHIEVE Partial Knee SystemDec 16, 2024
133 days to decisionK242307 · Product code: **NJD** · Orthopedic
Source: <https://www.510kdatabase.net/k242307/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Femorotibial, Unicompartmental/unicondylar, Uncemented, Porous-coated, Metal/polymer (NJD)
Date received	Aug 5, 2024
Decision date	Dec 16, 2024
Days to decision	133 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.netDevice record: <https://www.510kdatabase.net/k242307/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026