

K182301 PFC SIGMA Knee SystemNov 8, 2019
441 days to decisionK182301 · Product code: **JWH** · Orthopedic
Source: <https://www.510kdatabase.net/k182301/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Aug 24, 2018
Decision date	Nov 8, 2019
Days to decision	441 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	DePuy Orthopaedics, Inc.
Location	Warsaw, IN, US
Contact	Kathy Harris
510(k) history	206 submissions · 204 cleared · 1998-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k182301/> 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 26, 2026