FDA 510(k) Premarket Notification

K182301 PFC SIGMA Knee System

CLEARED

Nov 8, 2019
441 days to decision

K182301 · 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