

K180743 Balanced Knee Revision System - Offset Junction BoxJun 20, 2018
90 days to decisionK180743 · Product code: **JWH** · Orthopedic
Source: <https://www.510kdatabase.net/k180743/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Mar 22, 2018
Decision date	Jun 20, 2018
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ortho Development Corporation
Location	Draper, UT, US
Contact	Dan Petersen
510(k) history	14 submissions · 14 cleared · 2015-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k180743/> 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