

**K182085 Balanced Knee Revision System Trabecular Tibial
Cone Augments**Oct 31, 2018
90 days to decisionK182085 · Product code: **JWH** · Orthopedic
Source: <https://www.510kdatabase.net/k182085/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Aug 2, 2018
Decision date	Oct 31, 2018
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k182085/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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