

**K103837 BALANCED KNEE SYSTEM REVISION OFFSET TIBIA**Mar 24, 2011  
84 days to decisionK103837 · Product code: **JWH** · Orthopedic  
Source: <https://www.510kdatabase.net/k103837/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Dec 30, 2010
Decision date	Mar 24, 2011
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ortho Development</b>
Location	Draper, UT, US
Contact	TOM HAUETER
510(k) history	5 submissions · 5 cleared · 2011-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k103837/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 17, 2026