

**K163332 Apex Revision Knee System**Apr 26, 2017  
149 days to decisionK163332 · Product code: **JWH** · Orthopedic  
Source: <https://www.510kdatabase.net/k163332/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Nov 28, 2016
Decision date	Apr 26, 2017
Days to decision	149 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Omnilife Science</b>
Location	Raynham, MA, US
Contact	Christina Rovaldi
510(k) history	7 submissions · 7 cleared · 2007-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k163332/> 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 27, 2026