

**K191765 OMNI TiN Coated Apex Knee™ System**Sep 25, 2019  
86 days to decisionK191765 · Product code: **JWH** · Orthopedic  
Source: <https://www.510kdatabase.net/k191765/>**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	Jul 1, 2019
Decision date	Sep 25, 2019
Days to decision	86 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Omni Life Science, Inc.</b>
Location	Raynham, MA, US
Contact	Christina Rovaldi
510(k) history	21 submissions · 21 cleared · 2006-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k191765/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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