

**K161366 ConfoMIS iTotol Cruciate Retaining (CR) Knee Replacement System (iTotol CR KRS)**Jun 14, 2016  
28 days to decisionK161366 · Product code: **JWH** · Orthopedic  
Source: <https://www.510kdatabase.net/k161366/>**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	May 17, 2016
Decision date	Jun 14, 2016
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Conformis, Inc.</b>
Location	Foster City, CA, US
Contact	AMITA SHAH
510(k) history	60 submissions · 60 cleared · 2005-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161366/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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