

**K153721 iTotal Cruciate Retaining (CR) Knee Replacement System**Mar 25, 2016  
88 days to decisionK153721 · Product code: **JWH** · Orthopedic  
Source: <https://www.510kdatabase.net/k153721/>**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 28, 2015
Decision date	Mar 25, 2016
Days to decision	88 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/k153721/>, 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