

**K230846 iTotal Identity Knee Replacement System**Jul 17, 2023  
111 days to decisionK230846 · Product code: **JWH** · Orthopedic  
Source: <https://www.510kdatabase.net/k230846/>**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	Mar 28, 2023
Decision date	Jul 17, 2023
Days to decision	111 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Identity Imprint Knee Replacement System

**APPLICANT**

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Company	<b>Conformis, Inc.</b>
Location	Foster City, CA, US
Contact	Nancy Giezen
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/k230846/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 13, 2026