

**K122991 ITOTAL CRUCIATE RETAINING (CR) KNEE REPLACEMENT SYSTEM**Dec 20, 2012  
85 days to decisionK122991 · Product code: **JWH** · Orthopedic  
Source: <https://www.510kdatabase.net/k122991/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Sep 26, 2012
Decision date	Dec 20, 2012
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k122991/>, Data sourced from FDA 510(k) public records (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. - Generated May 18, 2026