

**K133560 ITOTAL CRUCIATE RETAINING KNEE REPLACEMENT SYSTEM**Mar 28, 2014  
128 days to decisionK133560 · Product code: **JWH** · Orthopedic  
Source: <https://www.510kdatabase.net/k133560/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Nov 20, 2013
Decision date	Mar 28, 2014
Days to decision	128 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/k133560/>, 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 17, 2026