

**K162719 iTotal® Hip Replacement System**Jun 14, 2017  
258 days to decisionK162719 · Product code: **LPH** · Orthopedic  
Source: <https://www.510kdatabase.net/k162719/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Metal/polymer, Porous Uncemented (LPH)
Date received	Sep 29, 2016
Decision date	Jun 14, 2017
Days to decision	258 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/k162719/> 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 16, 2026