

**K161184 iNSitu Total Hip System**Oct 14, 2016  
170 days to decisionK161184 · Product code: **LPH** · Orthopedic  
Source: <https://www.510kdatabase.net/k161184/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Metal/polymer, Porous Uncemented (LPH)
Date received	Apr 27, 2016
Decision date	Oct 14, 2016
Days to decision	170 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Theken Companies, LLC</b>
Location	Akron, OH, US
Contact	Dale Davison
510(k) history	4 submissions · 4 cleared · 2016-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161184/> 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 June 28, 2026