

K191936 iNSitu Total Hip SystemAug 20, 2019
32 days to decisionK191936 · Product code: **LPH** · Orthopedic
Source: <https://www.510kdatabase.net/k191936/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Hip, Semi-constrained, Metal/polymer, Porous Uncemented (LPH)
Date received	Jul 19, 2019
Decision date	Aug 20, 2019
Days to decision	32 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Thecken Companies, LLC
Location	Akron, OH, US
Contact	Garrett Spurgeon
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	Biovera
Contact	Bob Poggie

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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