

K192071 iNSitu Total Hip SystemAug 30, 2019
28 days to decisionK192071 · Product code: **LPH** · Orthopedic
Source: <https://www.510kdatabase.net/k192071/>**SUBMISSION DETAILS**

| | |
|-----------------------|---------------------------------------------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Prosthesis, Hip, Semi-constrained, Metal/polymer, Porous Uncemented (LPH) |
| Date received | Aug 2, 2019 |
| Decision date | Aug 30, 2019 |
| Days to decision | 28 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Theken Companies, LLC |
| Location | Akron, OH, US |
| Contact | Garrett Spurgeon |
| 510(k) history | 4 submissions · 4 cleared · 2016-2019 |

REGULATORY CONSULTANT

| | |
|-----------------|----------------------|
| Consulting firm | BioVera, Inc. |
| Contact | Robert A. 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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