

K190276 Provident II Hip StemMar 8, 2019
28 days to decisionK190276 · Product code: **LPH** · Orthopedic
Source: <https://www.510kdatabase.net/k190276/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Hip, Semi-constrained, Metal/polymer, Porous Uncemented (LPH)
Date received	Feb 8, 2019
Decision date	Mar 8, 2019
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Stelkast, Inc.
Location	Mcmurray, PA, US
Contact	David Stumpo
510(k) history	3 submissions · 3 cleared · 2016-2019

REGULATORY CONSULTANT

Consulting firm	Musculoskeletal Clinical Regulatory Advisers, LLC
Contact	Hollace Rhodes

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k190276/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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