

**K182705 Juveno Hip System Femoral Stem, b-ONE Primary
Acetabular System Cups**Feb 14, 2019
140 days to decisionK182705 · Product code: **LZO** · Orthopedic
Source: <https://www.510kdatabase.net/k182705/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Metal/ceramic/polymer, Cemented Or Non-porous, Uncemented (LZO)
Date received	Sep 27, 2018
Decision date	Feb 14, 2019
Days to decision	140 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	B-One Ortho, Corp.
Location	Cedar Knolls, NJ, US
Contact	Allison Gecik
510(k) history	12 submissions · 12 cleared · 2018-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k182705/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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