

**K202768 KOSMO Femoral Stem**Apr 1, 2021  
192 days to decisionK202768 · Product code: **LZO** · Orthopedic  
Source: <https://www.510kdatabase.net/k202768/>**SUBMISSION DETAILS**

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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 21, 2020
Decision date	Apr 1, 2021
Days to decision	192 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k202768/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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