

K240528 b-ONE® Total Hip SystemNov 15, 2024
266 days to decisionK240528 · Product code: **LZO** · Orthopedic
Source: <https://www.510kdatabase.net/k240528/>**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	Feb 23, 2024
Decision date	Nov 15, 2024
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	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/k240528/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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