

K173380 b-ONE® Total Hip SystemAug 30, 2018
304 days to decisionK173380 · Product code: **LZO** · Orthopedic
Source: <https://www.510kdatabase.net/k173380/>**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	Oct 30, 2017
Decision date	Aug 30, 2018
Days to decision	304 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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