

**K200959 BioloX® delta Ceramic Heads, BioloX® delta Option
Ceramic Heads MR Labeling**Jul 29, 2020
110 days to decisionK200959 · Product code: **LZO** · Orthopedic
Source: <https://www.510kdatabase.net/k200959/>**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	Apr 10, 2020
Decision date	Jul 29, 2020
Days to decision	110 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Biomet UK, Ltd.
Location	Warsaw, IN, US
Contact	Caleb Barylski
Website	http://www.biomet.co.uk/
510(k) history	3 submissions · 3 cleared · 2014-2020

Biomet UK, Ltd. is an orthopedic device manufacturer with a registered facility in Warsaw, US. Now part of Zimmer Biomet, the brand continues to operate under the parent company's global musculoskeletal platform. The company has received FDA 510(k) clearances from total submissions. All submissions focused on orthopedic devices, with clearances spanning 2014 to 2020. The company is currently inactive, with no new clearances recorded in the past five years. Historical cleared devices include ceramic femoral heads and partial knee replacement bearing systems. These products...