

**K964431 ZIRCONIA CERAMIC MODULAR HEADS (NORTON
ADVANCED CERAMICS)**Aug 11, 1997
279 days to decisionK964431 · Product code: **LZO** · Orthopedic
Source: <https://www.510kdatabase.net/k964431/>**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	Nov 5, 1996
Decision date	Aug 11, 1997
Days to decision	279 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biomet, Inc.
Location	Mchenry, IL, US
Contact	PATRICIA S BERES
Website	http://www.biomet.com/
510(k) history	440 submissions · 418 cleared · 1978-2024

Biomet, Inc. is an orthopedic medical device manufacturer based in McHenry, US. The company specializes in surgical implants, fixation systems, and trauma solutions. Biomet has maintained a strong FDA 510(k) regulatory record since its first clearance in 1978. The company has received FDA 510(k) clearances from total submissions. Orthopedic devices represent 88% of its submission portfolio, reflecting the company's core focus on joint reconstruction, trauma fixation, and surgical instrumentation. The latest clearance in 2024 demonstrates continued regulatory activity and ...

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Device record: <https://www.510kdatabase.net/k964431/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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