

K160071 StageOne Disposable Cement Spacer Molds for Temporary Hemi-Shoulder Prosthesis

Jun 16, 2016
155 days to decision

K160071 · Product code: **MBB** · Orthopedic
Source: <https://www.510kdatabase.net/k160071/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bone Cement, Antibiotic (MBB)
Date received	Jan 13, 2016
Decision date	Jun 16, 2016
Days to decision	155 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biomet, Inc.
Location	Mchenry, IL, US
Contact	Carmen Albany
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/k160071/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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