

K161273 StageOne Disposable Cement Spacer Molds for Temporary Knee Prosthesis

Jan 25, 2017
265 days to decisionK161273 · Product code: **MBB** · Orthopedic
Source: <https://www.510kdatabase.net/k161273/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bone Cement, Antibiotic (MBB)
Date received	May 5, 2016
Decision date	Jan 25, 2017
Days to decision	265 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/k161273/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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