FDA 510(k) Premarket Notification

CLEARED

K221968 StageOne™ Shoulder Cement Spacer Molds

Sep 15, 2022
72 days to decision

K221968 · Product code: **MBB** · Orthopedic
Source: https://www.510kdatabase.net/k221968/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bone Cement, Antibiotic (MBB)
Date received	Jul 5, 2022
Decision date	Sep 15, 2022
Days to decision	72 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Biomet, Inc.**
Location	Mchenry, IL, US
Contact	Neha Sreenath
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 ...