FDA 510(k) Premarket Notification

K030178 CALCIGEN PSI BONE GRAFT SUBSTITUTE

CLEARED

Feb 26, 2003
40 days to decision

K030178 · Product code: **MQV** · Orthopedic
Source: https://www.510kdatabase.net/k030178/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filler, Bone Void, Calcium Compound (MQV)
Date received	Jan 17, 2003
Decision date	Feb 26, 2003
Days to decision	40 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Biomet, Inc.**
Location	Mchenry, IL, US
Contact	MARY VERSTYNEN
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 ...