

K072330 CONTROLLED DELIVERY FOR OSTEOPLASTY (CDO SYSTEM) AND GRAFT PREPARATION SYSTEMDec 6, 2007
108 days to decisionK072330 · Product code: **FMF** · General Hospital
Source: <https://www.510kdatabase.net/k072330/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Aug 20, 2007
Decision date	Dec 6, 2007
Days to decision	108 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Biomet, Inc.
Location	McHenry, IL, US
Contact	PAULA DEMING
Website	http://www.biomet.com/
510(k) history	441 submissions · 419 cleared · 1978-2026

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 ...