

**K011399 BIOMET CRANIOFACIAL ACRYLIC CEMENT**May 5, 2003  
728 days to decisionK011399 · Product code: **GXP** · Neurology  
Source: <https://www.510kdatabase.net/k011399/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Methyl Methacrylate For Cranioplasty (GXP)
Date received	May 7, 2001
Decision date	May 5, 2003
Days to decision	728 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biomet, Inc.</b>
Location	Mchenry, IL, US
Contact	MICHELLE L MCKINLEY
Website	<a href="http://www.biomet.com/">http://www.biomet.com/</a>
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 ...