

**K253854 MONTAGE XT Cranial Cement**Jan 2, 2026  
30 days to decisionK253854 · Product code: **GXP** · Neurology  
Source: <https://www.510kdatabase.net/k253854/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Methyl Methacrylate For Cranioplasty (GXP)
Date received	Dec 3, 2025
Decision date	Jan 2, 2026
Days to decision	30 days
Third-party review	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Orthocon, Inc.</b>
Location	Stamford, CT, US
Contact	Alyssa McDermott
Website	<a href="https://www.orthocon.com">https://www.orthocon.com</a>
510(k) history	34 submissions · 34 cleared · 2006-2026

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