

K221933 MONTAGE Settable, Resorbable Bone PuttyJan 13, 2023
196 days to decisionK221933 · Product code: **GXP** · Neurology
Source: <https://www.510kdatabase.net/k221933/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Methyl Methacrylate For Cranioplasty (GXP)
Date received	Jul 1, 2022
Decision date	Jan 13, 2023
Days to decision	196 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Orthocon, Inc.
Location	Stamford, CT, US
Contact	Aniq Darr
Website	https://www.orthocon.com
510(k) history	34 submissions · 34 cleared · 2006-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k221933/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026