

**K253447 Montage Flowable Settable, Resorbable Bone Paste
(Burr Hole Cover)**Mar 16, 2026
165 days to decisionK253447 · Product code: **GXR** · Neurology
Source: <https://www.510kdatabase.net/k253447/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cover, Burr Hole (GXR)
Date received	Oct 2, 2025
Decision date	Mar 16, 2026
Days to decision	165 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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