

K242216 GENTAFIX® (1, 3, 3MV)Dec 18, 2024
142 days to decisionK242216 · Product code: **MBB** · Orthopedic
Source: <https://www.510kdatabase.net/k242216/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bone Cement, Antibiotic (MBB)
Date received	Jul 29, 2024
Decision date	Dec 18, 2024
Days to decision	142 days
Third-party review	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Teknimed Sas
Location	Round Rock, TX, US
Contact	Claudine Lavergne
510(k) history	3 submissions · 3 cleared · 2011-2024

REGULATORY CONSULTANT

Consulting firm	RQMIS, Inc.
Contact	Barry Sands

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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