FDA 510(k) Premarket Notification

K242216 GENTAFIX® (1, 3, 3MV)

CLEARED

Dec 18, 2024
142 days to decision

K242216 · 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