

K233490 SIGNAFUSE Bioactive Strip (SBS)Dec 5, 2023
39 days to decisionK233490 · Product code: **MQV** · Orthopedic
Source: <https://www.510kdatabase.net/k233490/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filler, Bone Void, Calcium Compound (MQV)
Date received	Oct 27, 2023
Decision date	Dec 5, 2023
Days to decision	39 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	SIGNAFUSE Putty

APPLICANT

Company	Bioventus, LLC
Location	Durham, NC, US
Contact	Kellie Stefaniak
510(k) history	5 submissions · 5 cleared · 2017-2025

REGULATORY CONSULTANT

Consulting firm	Bruder Consulting & Venture Group
Contact	Scott Bruder

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

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