

K241167 BioSphere PuttyDec 20, 2024
238 days to decisionK241167 · Product code: **MQV** · Orthopedic
Source: <https://www.510kdatabase.net/k241167/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filler, Bone Void, Calcium Compound (MQV)
Date received	Apr 26, 2024
Decision date	Dec 20, 2024
Days to decision	238 days
Third-party review	No
PCCP authorized	No
Summary / Statement	Summary
Other names	BioSphere MIS Putty

APPLICANT

Company	Synergy Biomedical
Location	Collegeville, PA, US
Contact	Kevin Booth
510(k) history	2 submissions · 2 cleared · 2018-2024

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](https://accessdata.fda.gov)

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