FDA 510(k) Premarket Notification

# K240459 Cerament Bone Void Filler

**CLEARED**

Mar 5, 2024
18 days to decision

K240459 · Product code: **MQV** · Orthopedic
Source: https://www.510kdatabase.net/k240459/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Filler, Bone Void, Calcium Compound (MQV) |
| Date received | Feb 16, 2024 |
| Decision date | Mar 5, 2024 |
| Days to decision | 18 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Bonesupport AB** |
| Location | Minneapolis, MN, US |
| Contact | Blerta Shuka |
| 510(k) history | 7 submissions · 6 cleared · 2005-2024 |

## 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