

K241564 Actifuse ABXAug 2, 2024
63 days to decisionK241564 · Product code: **MQV** · Orthopedic
Source: <https://www.510kdatabase.net/k241564/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Filler, Bone Void, Calcium Compound (MQV) |
| Date received | May 31, 2024 |
| Decision date | Aug 2, 2024 |
| Days to decision | 63 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |
| Other names | Actifuse MIS; Actifuse Shape; ALTAPORE; ALTAPORE SHAPE; ALTAPORE MIS |

APPLICANT

| | |
|----------------|---|
| Company | Baxter Healthcare Corporation |
| Location | Round Lake, IL, US |
| Contact | Phillip Romei |
| 510(k) history | 61 submissions · 60 cleared · 2004-2025 |

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