

**K040755 EXACTECH RESORBABLE ROOM TEMPERATURE
BONE PASTE**Jun 17, 2004
85 days to decisionK040755 · Product code: **MQV** · Orthopedic
Source: <https://www.510kdatabase.net/k040755/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Filler, Bone Void, Calcium Compound (MQV) |
| Date received | Mar 24, 2004 |
| Decision date | Jun 17, 2004 |
| Days to decision | 85 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Exactech, Inc. |
| Location | Gainesville, FL, US |
| Contact | REBECCA ROBERTS |
| Website | https://www.exac.com/ |
| 510(k) history | 186 submissions · 174 cleared · 1986-2026 |

Exactech, Inc. operates with a manufacturing facility in Gainesville, US. The company does not offer direct sales or distribution in the United States. Product inquiries and safety concerns are handled through designated company contacts. Exactech has submitted FDA 510(k) applications, resulting in cleared devices. The company's regulatory activity spans from 1986 to 2026, demonstrating sustained engagement with FDA clearance processes. Orthopedic devices represent the dominant focus of the company's portfolio, accounting for approximately 99% of submissions. Recent FDA 5...