

K012254 VBROct 16, 2001
90 days to decisionK012254 · Product code: **MQP** · Orthopedic
Source: <https://www.510kdatabase.net/k012254/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Spinal Vertebral Body Replacement Device (MQP) |
| Date received | Jul 18, 2001 |
| Decision date | Oct 16, 2001 |
| Days to decision | 90 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Osteotech, Inc. |
| Location | San Mateo, CA, US |
| Contact | KIM THURMAN |
| 510(k) history | 24 submissions · 21 cleared · 1985-2008 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k012254/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026