

K012125 OPUS MAGNUM ANCHOR & INSERTERSep 17, 2001
73 days to decisionK012125 · Product code: **HTY** · Orthopedic
Source: <https://www.510kdatabase.net/k012125/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Pin, Fixation, Smooth (HTY) |
| Date received | Jul 6, 2001 |
| Decision date | Sep 17, 2001 |
| Days to decision | 73 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Opus Medical, Inc. |
| Location | Albuquerque,, NM, US |
| Contact | MARK RITCHART |
| 510(k) history | 13 submissions · 13 cleared · 2001-2004 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k012125/> 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