

K151615 TiTHON Staple with OsseoTi TechnologyOct 2, 2015
109 days to decisionK151615 · Product code: **JDR** · Orthopedic
Source: <https://www.510kdatabase.net/k151615/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Staple, Fixation, Bone (JDR) |
| Date received | Jun 15, 2015 |
| Decision date | Oct 2, 2015 |
| Days to decision | 109 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Biomet Manufacturing Corp |
| Location | Warsaw, IN, US |
| Contact | Patricia Sandborn Beres |
| 510(k) history | 93 submissions · 93 cleared · 2004-2023 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k151615/> 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 17, 2026