FDA 510(k) Premarket Notification

# K131640 SMOOTH OR THREADED METALLIC BONE FASTENER

**CLEARED**

Oct 16, 2013
134 days to decision

K131640 · Product code: **HTY** · Orthopedic
Source: https://www.510kdatabase.net/k131640/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Pin, Fixation, Smooth (HTY) |
| Date received | Jun 4, 2013 |
| Decision date | Oct 16, 2013 |
| Days to decision | 134 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Biomedical Ent., Inc.** |
| Location | San Antonio, TX, US |
| Contact | JOE SOWARD |
| 510(k) history | 13 submissions · 13 cleared · 1996-2014 |

**510k Database** - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k131640/ 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