FDA 510(k) Premarket Notification

**CLEARED**

# K100012 GRYPHON T BR DS ANCHOR W/ORTHOCORD, GRYPHON T BR ANCHOR W /ORTHOCORD, GRYPHON P BR DS ANCHOR W/ORTHOCORD, GRYPHON P BR A

Apr 30, 2010
116 days to decision

K100012 · Product code: **MAI** · Orthopedic
Source: https://www.510kdatabase.net/k100012/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Fastener, Fixation, Biodegradable, Soft Tissue (MAI) |
| Date received | Jan 4, 2010 |
| Decision date | Apr 30, 2010 |
| Days to decision | 116 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Depuy Mitek, A Johnson & Johnson Company** |
| Location | Norwood, MA, US |
| Contact | Ruth Forstadt |
| 510(k) history | 58 submissions · 58 cleared · 2004-2015 |