

**K003756 BIOSORBFX TACK AND BIOSORBPDX TACK
BIOABSORBABLE FIXATION FASTENER, USED WITH PLATES**Jan 3, 2001
28 days to decisionK003756 · Product code: JEY · Dental
Source: <https://www.510kdatabase.net/k003756/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Plate, Bone (JEY) |
| Date received | Dec 6, 2000 |
| Decision date | Jan 3, 2001 |
| Days to decision | 28 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Bionx Implants, Inc. |
| Location | Tampere, Fl |
| Contact | DAVID W ANDERSON |
| 510(k) history | 18 submissions · 18 cleared · 1998-2002 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k003756/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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