

K010687 BIOSORBFX AND BIOSORBPDX MESHMar 14, 2001
6 days to decisionK010687 · Product code: **JEY** · DentalSource: <https://www.510kdatabase.net/k010687/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Plate, Bone (JEY) |
| Date received | Mar 8, 2001 |
| Decision date | Mar 14, 2001 |
| Days to decision | 6 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Bionx Implants, Inc. |
| Location | Tampere, FI |
| Contact | TUIJA ANNALA |
| 510(k) history | 18 submissions · 18 cleared · 1998-2002 |

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