

K031467 GLASIONOMER FX-IIJul 17, 2003
70 days to decisionK031467 · Product code: **EMA** · Dental
Source: <https://www.510kdatabase.net/k031467/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Cement, Dental (EMA) |
| Date received | May 8, 2003 |
| Decision date | Jul 17, 2003 |
| Days to decision | 70 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Shofu Dental Corp. |
| Location | Mchenry, IL, US |
| Contact | ROBERT NOBLE |
| 510(k) history | 59 submissions · 59 cleared · 1981-2011 |

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