

K945451 HI DENSE, GLASS IONOMER SILVER REINFORCED RESTORATIVEFeb 27, 1995
112 days to decisionK945451 · Product code: **EMA** · Dental
Source: <https://www.510kdatabase.net/k945451/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Cement, Dental (EMA) |
| Date received | Nov 7, 1994 |
| Decision date | Feb 27, 1995 |
| Days to decision | 112 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k945451/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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