

K213965 BeautiBond XtremeMar 18, 2022
88 days to decisionK213965 · Product code: **KLE** · Dental
Source: <https://www.510kdatabase.net/k213965/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Agent, Tooth Bonding, Resin (KLE) |
| Date received | Dec 20, 2021 |
| Decision date | Mar 18, 2022 |
| Days to decision | 88 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Shofu Dental Corporation |
| Location | San Marcos, CA, US |
| Contact | Mauro Malzyner |
| 510(k) history | 38 submissions · 38 cleared · 2011-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213965/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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