

K080068 BEAUTIFIL OPAQUERFeb 28, 2008
49 days to decisionK080068 · Product code: **EBF** · Dental
Source: <https://www.510kdatabase.net/k080068/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Material, Tooth Shade, Resin (EBF) |
| Date received | Jan 10, 2008 |
| Decision date | Feb 28, 2008 |
| Days to decision | 49 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

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

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