

K001913 CLEARFIL ST OPAQUERAug 4, 2000
42 days to decisionK001913 · Product code: **EBF** · Dental
Source: <https://www.510kdatabase.net/k001913/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Material, Tooth Shade, Resin (EBF) |
| Date received | Jun 23, 2000 |
| Decision date | Aug 4, 2000 |
| Days to decision | 42 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Kuraray Company, Ltd. |
| Location | New York, NY, US |
| Contact | KOICHI K IKUCHI |
| 510(k) history | 10 submissions · 10 cleared · 1994-2000 |

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