

K022675 PRIME-DENT AUTOMIX DUAL CURE CORE BUILD UP MATERIALNov 7, 2002
87 days to decisionK022675 · Product code: **EBF** · Dental
Source: <https://www.510kdatabase.net/k022675/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Material, Tooth Shade, Resin (EBF) |
| Date received | Aug 12, 2002 |
| Decision date | Nov 7, 2002 |
| Days to decision | 87 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Prime Dental Manufacturing, Inc. |
| Location | Chicago, IL, US |
| Contact | ROLANDO MARASIGAN |
| 510(k) history | 9 submissions · 9 cleared · 2000-2012 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k022675/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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