

**K112044 ANAXBLEND MODEL 20XXX (SEVERAL), ANAXGUM
MODEL 25XXX (U), MOCK-UP DIRECT MODEL 240XXX (U),
MOCK-UP DIRECT FLOW MODEL 24A**

Jan 26, 2012
192 days to decision

K112044 · Product code: **EBF** · Dental
Source: <https://www.510kdatabase.net/k112044/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Jul 18, 2011
Decision date	Jan 26, 2012
Days to decision	192 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Anaxdent GmbH
Location	Washington, DC, US
Contact	JOHN BALISTRERI
510(k) history	2 submissions · 2 cleared · 2002-2012

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k112044/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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