

**K012160 COMPCORE AF COMPOSITE CORE BUILD-UP  
MATERIAL, MODEL 3001408**Sep 27, 2001  
78 days to decisionK012160 · Product code: **EBF** · Dental  
Source: <https://www.510kdatabase.net/k012160/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Jul 11, 2001
Decision date	Sep 27, 2001
Days to decision	78 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Premier Dental Products Co.</b>
Location	Mchenry, IL, US
Contact	BARRY HALE
510(k) history	41 submissions · 41 cleared · 1977-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k012160/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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