

K182065 EVOLUX CAD/CAM PMMA BLOCKSDec 13, 2018
134 days to decisionK182065 · Product code: **EBG** · Dental
Source: <https://www.510kdatabase.net/k182065/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Crown And Bridge, Temporary, Resin (EBG)
Date received	Aug 1, 2018
Decision date	Dec 13, 2018
Days to decision	134 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Blue Dent Dental
Location	Pirassununga, BR
Contact	Adriana Paula T I Gomes
510(k) history	1 submissions · 1 cleared · 2018-2018

REGULATORY CONSULTANT

Consulting firm	Passarini Regulatory Affairs of America, LLC
Contact	Mauro Malzyner

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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