

K211345 C-30 Crown KitNov 24, 2021
205 days to decisionK211345 · Product code: **EBF** · Dental
Source: <https://www.510kdatabase.net/k211345/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	May 3, 2021
Decision date	Nov 24, 2021
Days to decision	205 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Perfect Fit Crowns, LLC
Location	Royal Palm Beach, FL, US
Contact	Steve Ziskind
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Evo820, LLC
Contact	Tim Torbenson

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211345/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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