

K193496 CharmFilMay 6, 2020
141 days to decisionK193496 · Product code: **EBF** · Dental
Source: <https://www.510kdatabase.net/k193496/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Dec 17, 2019
Decision date	May 6, 2020
Days to decision	141 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dentkist, Inc.
Location	Gunpo-Si, KR
Contact	Shin Haeng Lee
510(k) history	2 submissions · 2 cleared · 2016-2020

REGULATORY CONSULTANT

Consulting firm	Plusglobal
Contact	Peter Chung

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/k193496/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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