

K202965 CURA-TempDec 21, 2022
812 days to decisionK202965 · Product code: **EBG** · Dental
Source: <https://www.510kdatabase.net/k202965/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Crown And Bridge, Temporary, Resin (EBG)
Date received	Sep 30, 2020
Decision date	Dec 21, 2022
Days to decision	812 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Mgnewton , Ltd.
Location	Gyeongsan-Si, KR
Contact	Byoung Wook Ahn
510(k) history	2 submissions · 2 cleared · 2022-2023

REGULATORY CONSULTANT

Consulting firm	LK Consulting Group USA, Inc.
Contact	Priscilla Chung

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

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