

K201563 PuRE PMMA DiscApr 9, 2021
303 days to decisionK201563 · Product code: **EBG** · Dental
Source: <https://www.510kdatabase.net/k201563/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Crown And Bridge, Temporary, Resin (EBG)
Date received	Jun 10, 2020
Decision date	Apr 9, 2021
Days to decision	303 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Quest Dental USA Corp.
Location	Irvine, CA, US
Contact	Hiroataka Mori
510(k) history	2 submissions · 2 cleared · 2017-2021

REGULATORY CONSULTANT

Consulting firm	Globizz Corporation
Contact	Takahiro Haruyama

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/k201563/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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