

K230487 Dental Lithium Disilicate Glass-CeramicJul 3, 2023
130 days to decisionK230487 · Product code: **EIH** · DentalSource: <https://www.510kdatabase.net/k230487/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powder, Porcelain (EIH)
Date received	Feb 23, 2023
Decision date	Jul 3, 2023
Days to decision	130 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Fuzhou Rick Brown Biomaterials Co., Ltd.
Location	Fuzhou, CN
Contact	Zhong Huang
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Shenzhen Huatongwei International Inspection Co., Ltd.
Contact	Sherry Kang

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

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