

K214003 Dental Zirconia Pre-shaded BlockFeb 18, 2022
59 days to decisionK214003 · Product code: **EIH** · Dental
Source: <https://www.510kdatabase.net/k214003/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powder, Porcelain (EIH)
Date received	Dec 21, 2021
Decision date	Feb 18, 2022
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shenzhen Yurucheng Dental Materials Co., Ltd.
Location	Shenzhen, CN
Contact	Fiya Liao
510(k) history	3 submissions · 3 cleared · 2022-2023

REGULATORY CONSULTANT

Consulting firm	Shenzhen Joyantech Consulting Co., Ltd.
Contact	Grace Liu

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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