

K222513 Glass CeramicsFeb 10, 2023
175 days to decisionK222513 · Product code: **EIH** · DentalSource: <https://www.510kdatabase.net/k222513/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powder, Porcelain (EIH)
Date received	Aug 19, 2022
Decision date	Feb 10, 2023
Days to decision	175 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Yilink (Tianjin) Biotechnology Co., Ltd.
Location	Tianjin, CN
Contact	Yaqiong Zhu
510(k) history	3 submissions · 3 cleared · 2022-2024

REGULATORY CONSULTANT

Consulting firm	Chenhe Medical Consulting Co., Ltd.
Contact	Jennifer 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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