

K230003 Topzir Dental Zirconia Blank & Dental Zirconia Pre-Shaded BlankMar 31, 2023
87 days to decisionK230003 · Product code: **EIH** · Dental
Source: <https://www.510kdatabase.net/k230003/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powder, Porcelain (EIH)
Date received	Jan 3, 2023
Decision date	Mar 31, 2023
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Topzir Biotech Co., Ltd.
Location	Guangzhou, CN
Contact	Hui Liu
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Guangzhou Junyi Information Technology Co., Ltd.
Contact	Shanfeng Jiang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k230003/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026