FDA 510(k) Premarket Notification

K222520 Zirconia Block

CLEARED

Nov 14, 2022
87 days to decision

K222520 · Product code: **EIH** · Dental
Source: https://www.510kdatabase.net/k222520/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powder, Porcelain (EIH)
Date received	Aug 19, 2022
Decision date	Nov 14, 2022
Days to decision	87 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