FDA 510(k) Premarket Notification

K233125 Zirconia Block

CLEARED

Jan 12, 2024
107 days to decision

K233125 · Product code: **EIH** · Dental
Source: https://www.510kdatabase.net/k233125/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powder, Porcelain (EIH)
Date received	Sep 27, 2023
Decision date	Jan 12, 2024
Days to decision	107 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Hangzhou Ivista Medical Devices Co., Ltd.**
Location	Hangzhou, CN
Contact	Yao Cheng
510(k) history	1 submissions · 1 cleared · 2024-2024