FDA 510(k) Premarket Notification

K222891 Dental Desensitizer

CLEARED

May 25, 2023
244 days to decision

K222891 · Product code: **LBH** · Dental
Source: https://www.510kdatabase.net/k222891/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Varnish, Cavity (LBH)
Date received	Sep 23, 2022
Decision date	May 25, 2023
Days to decision	244 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Guangzhou Beogene Biotech Co., Ltd.**
Location	Guangzhou, CN
Contact	Duan Qiangqiang
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**Feiying Drug & Medical Consulting Technical Service Group**
Contact	Tracy Che

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov