

K222891 Dental DesensitizerMay 25, 2023
244 days to decisionK222891 · Product code: **LBH** · Dental
Source: <https://www.510kdatabase.net/k222891/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| 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

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|-----------------|--|
| Consulting firm | Feiyang 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](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k222891/> 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