

K221194 LEDEXSep 16, 2022
144 days to decisionK221194 · Product code: **EBZ** · DentalSource: <https://www.510kdatabase.net/k221194/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Abbreviated |
| Device classification | Activator, Ultraviolet, For Polymerization (EBZ) |
| Date received | Apr 25, 2022 |
| Decision date | Sep 16, 2022 |
| Days to decision | 144 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Dentmate Technology Co. , Ltd. |
| Location | Sanchung, TW |
| Contact | Cheng-Feng Chou |
| 510(k) history | 4 submissions · 4 cleared · 2008-2022 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k221194/> 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 26, 2026