

K210189 Pac-Dent Denture Base ResinJul 28, 2021
184 days to decisionK210189 · Product code: **EBI** · DentalSource: <https://www.510kdatabase.net/k210189/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Resin, Denture, Relining, Repairing, Rebasing (EBI) |
| Date received | Jan 25, 2021 |
| Decision date | Jul 28, 2021 |
| Days to decision | 184 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Pac-Dent, Inc. |
| Location | Brea, CA, US |
| Contact | Jingtian Peng |
| 510(k) history | 8 submissions · 8 cleared · 2020-2022 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k210189/> 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