

K250222 SDF ProMay 7, 2025
100 days to decisionK250222 · Product code: **PHR** · Dental
Source: <https://www.510kdatabase.net/k250222/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Diammine Silver Fluoride Dental Hypersensitivity Varnish (PHR) |
| Date received | Jan 27, 2025 |
| Decision date | May 7, 2025 |
| Days to decision | 100 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Belport Company, Inc., Gingi-Pak |
| Location | Camarillo, CA, US |
| Contact | Peng Jingtian |
| 510(k) history | 11 submissions · 11 cleared · 2020-2026 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250222/> 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 14, 2026