

K241489 ReminGelJan 8, 2025
229 days to decisionK241489 · Product code: **LBH** · Dental
Source: <https://www.510kdatabase.net/k241489/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Varnish, Cavity (LBH) |
| Date received | May 24, 2024 |
| Decision date | Jan 8, 2025 |
| Days to decision | 229 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Inter-Med, Inc. |
| Location | Racine, WI, US |
| Contact | Alex Johnson |
| 510(k) history | 8 submissions · 8 cleared · 2009-2026 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k241489/> 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 13, 2026