

K082594 REMESENSEMar 19, 2009
192 days to decisionK082594 · Product code: **LBH** · Dental
Source: <https://www.510kdatabase.net/k082594/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Varnish, Cavity (LBH) |
| Date received | Sep 8, 2008 |
| Decision date | Mar 19, 2009 |
| Days to decision | 192 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Remedent NV |
| Location | Lake Forest, CA, US |
| Contact | WILLIAM GREENROSE |
| 510(k) history | 2 submissions · 2 cleared · 2003-2009 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k082594/> 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 June 23, 2026