

**K122708 REMESENSE FOR SENSITIVE TEETH**Jan 14, 2013  
132 days to decisionK122708 · Product code: **LBH** · Dental  
Source: <https://www.510kdatabase.net/k122708/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Varnish, Cavity (LBH)              |
| Date received         | Sep 4, 2012                        |
| Decision date         | Jan 14, 2013                       |
| Days to decision      | 132 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Sylphar N.V.</b>                   |
| Location       | Rome, IT                              |
| Contact        | ROGER GRAY                            |
| 510(k) history | 2 submissions · 2 cleared · 2013-2014 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k122708/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 7, 2026