

**K913853 FISSURE SEALER**Aug 27, 1992  
366 days to decisionK913853 · Product code: **EBC** · Dental  
Source: <https://www.510kdatabase.net/k913853/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)              |
| Submission type       | Traditional                                     |
| Device classification | Sealant, Pit And Fissure, And Conditioner (EBC) |
| Date received         | Aug 27, 1991                                    |
| Decision date         | Aug 27, 1992                                    |
| Days to decision      | 366 days  |
| Third-party review    | No  |
| Summary / Statement   | Statement                                       |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Ortho Source</b>                   |
| Location       | North Hollywood, CA, US               |
| Contact        | ANDREA G MUSTACHIO                    |
| 510(k) history | 9 submissions · 9 cleared · 1986-1992 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k913853/> 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 July 3, 2026