

**K003426 ALGINATE IMPRESSION MATERIAL**Jan 23, 2001  
81 days to decisionK003426 · Product code: **ELW** · Dental  
Source: <https://www.510kdatabase.net/k003426/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Material, Impression (ELW)         |
| Date received         | Nov 3, 2000                        |
| Decision date         | Jan 23, 2001                       |
| Days to decision      | 81 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Statement                          |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Rite-Dent Manufacturing Corp.</b>  |
| Location       | Hialeah, FL, US                       |
| Contact        | CESAR E VELIZ                         |
| 510(k) history | 7 submissions · 7 cleared · 2001-2002 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k003426/> 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 2, 2026