

**K894058 ISODENT**Dec 21, 1989  
197 days to decisionK894058 · Product code: **EIA** · DentalSource: <https://www.510kdatabase.net/k894058/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Unit, Operative Dental (EIA)       |
| Date received         | Jun 7, 1989                        |
| Decision date         | Dec 21, 1989                       |
| Days to decision      | 197 days                           |
| Third-party review    | No                                 |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Eurodent, Inc.</b>                 |
| Location       | Mchenry, IL, US                       |
| Contact        | ALDO MARUCCHI-FOINO                   |
| 510(k) history | 5 submissions · 5 cleared · 1979-1989 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k894058/>; 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 4, 2026