

**K081699 PLANMECA SOVEREIGN**Aug 29, 2008  
73 days to decisionK081699 · Product code: **EIA** · DentalSource: <https://www.510kdatabase.net/k081699/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Unit, Operative Dental (EIA)       |
| Date received         | Jun 17, 2008                       |
| Decision date         | Aug 29, 2008                       |
| Days to decision      | 73 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---|
| Company        | <b>Planmeca USA, Inc.</b>               |
| Location       | Mchenry, IL, US                         |
| Contact        | BOB PIENKOWSKI                          |
| 510(k) history | 13 submissions · 13 cleared · 1984-2011 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k081699/> 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 May 17, 2026