

**K010381 D.SIGN 30**Mar 6, 2001  
26 days to decisionK010381 · Product code: **EJH** · DentalSource: <https://www.510kdatabase.net/k010381/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Alloy, Metal, Base (EJH)           |
| Date received         | Feb 8, 2001                        |
| Decision date         | Mar 6, 2001                        |
| Days to decision      | 26 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Statement                          |

**APPLICANT**

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|----------------|---|
| Company        | <b>Ivoclar North America, Inc.</b>        |
| Location       | Amherst, NY, US                           |
| Contact        | ANDY GULATI                               |
| 510(k) history | 131 submissions · 131 cleared · 1989-2001 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k010381/> 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