

**K032493 ALEXANDER**Sep 4, 2003  
23 days to decisionK032493 · Product code: **EJT** · DentalSource: <https://www.510kdatabase.net/k032493/>**SUBMISSION DETAILS**

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|                       |                                     |
|-----------------------|-------------------------------------|
| Decision              | Substantially Equivalent (Cleared)  |
| Submission type       | Traditional                         |
| Device classification | Alloy, Gold-based Noble Metal (EJT) |
| Date received         | Aug 12, 2003                        |
| Decision date         | Sep 4, 2003                         |
| Days to decision      | 23 days                             |
| Third-party review    | No                                  |
| Summary / Statement   | Statement                           |

**APPLICANT**

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|----------------|---|
| Company        | <b>Ivoclar Vivadent, Inc.</b>                                 |
| Location       | Amherst, NY, US   |
| Contact        | ANDERJEET S GULATI  |
| Website        | <a href="https://www.ivoclar.com">https://www.ivoclar.com</a> |
| 510(k) history | 65 submissions · 65 cleared · 2001-2026                       |

Ivoclar Vivadent, Inc. is a dental solutions provider based in Amherst, US. The company develops modern products for dental practitioners and laboratory technicians. The company has received FDA 510(k) clearances from total submissions since 2001. Dental devices represent 97% of its regulatory portfolio. The latest clearance was issued in 2026, confirming active market engagement. Recent cleared devices include restorative materials, adhesives, CAD-on restorations, bulk-fill composites, and curing lights. The product portfolio spans chairside and laboratory workflows for ...

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