

**K040951 SR ADORO**May 19, 2004  
37 days to decisionK040951 · Product code: **EBG** · Dental  
Source: <https://www.510kdatabase.net/k040951/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)       |
| Submission type       | Traditional                              |
| Device classification | Crown And Bridge, Temporary, Resin (EBG) |
| Date received         | Apr 12, 2004                             |
| Decision date         | May 19, 2004                             |
| Days to decision      | 37 days                                  |
| Third-party review    | No                                       |
| Summary / Statement   | Statement                                |

**APPLICANT**

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|----------------|---|
| Company        | <b>Ivoclar Vivadent, Inc.</b>                                 |
| Location       | Amherst, NY, US   |
| Contact        | DONNA MARIE HARTNETT  |
| 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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