

**K042846 SYSTEMP.LINK**Dec 20, 2004  
66 days to decisionK042846 · Product code: **EMA** · Dental  
Source: <https://www.510kdatabase.net/k042846/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Dental (EMA)
Date received	Oct 15, 2004
Decision date	Dec 20, 2004
Days to decision	66 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 M 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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