

K030435 BIOUNIVERSAL PKFApr 15, 2003
64 days to decisionK030435 · Product code: **EJT** · DentalSource: <https://www.510kdatabase.net/k030435/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Alloy, Gold-based Noble Metal (EJT)
Date received	Feb 10, 2003
Decision date	Apr 15, 2003
Days to decision	64 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Ivoclar Vivadent, Inc.
Location	Amherst, NY, US
Contact	ANDERJEET GULATI
Website	https://www.ivoclar.com
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 ...
