FDA 510(k) Premarket Notification

K023035 SR VIVOTAC/SR ORTHOTAC, MODIFIER MONOMER & POLYMER

CLEARED

Dec 2, 2002
81 days to decision

K023035 · Product code: **ELM** · Dental
Source: https://www.510kdatabase.net/k023035/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Denture, Plastic, Teeth (ELM)
Date received	Sep 12, 2002
Decision date	Dec 2, 2002
Days to decision	81 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ivoclar Vivadent, Inc.**
Location	Amherst, NY, US
Contact	DONNA MARIE HARTNETT
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 ...