FDA 510(k) Premarket Notification

K030922 VIVASENS

CLEARED

Oct 17, 2003
207 days to decision

K030922 · Product code: **LBH** · Dental
Source: https://www.510kdatabase.net/k030922/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Varnish, Cavity (LBH)
Date received	Mar 24, 2003
Decision date	Oct 17, 2003
Days to decision	207 days
Third-party review	No
Summary / Statement	Statement

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 ...