FDA 510(k) Premarket Notification

K103391 IVOBASE HYBRID, IVOBASE HIGH IMPACT

CLEARED

Feb 17, 2011
90 days to decision

K103391 · Product code: **EBI** · Dental
Source: https://www.510kdatabase.net/k103391/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Resin, Denture, Relining, Repairing, Rebasing (EBI)
Date received	Nov 19, 2010
Decision date	Feb 17, 2011
Days to decision	90 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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