

K153753 TelioCAD MultiApr 12, 2016
105 days to decisionK153753 · Product code: **EBG** · Dental
Source: <https://www.510kdatabase.net/k153753/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Crown And Bridge, Temporary, Resin (EBG)
Date received	Dec 29, 2015
Decision date	Apr 12, 2016
Days to decision	105 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 ...
