

K090843 AMARIS GINGIVA OPAQUERJun 17, 2009
82 days to decisionK090843 · Product code: **EBF** · DentalSource: <https://www.510kdatabase.net/k090843/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Mar 27, 2009
Decision date	Jun 17, 2009
Days to decision	82 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Voco GmbH
Location	Denver, CO, US
Contact	M. TH. PLAUMANN
Website	https://www.voco.dental
510(k) history	119 submissions · 119 cleared · 1991-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k090843/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 22, 2026