

K974465 SYNERGYMar 9, 1998
103 days to decisionK974465 · Product code: **EBF** · DentalSource: <https://www.510kdatabase.net/k974465/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Nov 26, 1997
Decision date	Mar 9, 1998
Days to decision	103 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Coltene/Whaledent, Inc.
Location	New York, NY, US
Contact	H.J. VOLGELSTEIN
Website	https://ap.coltene.com/
510(k) history	21 submissions · 21 cleared · 1991-2007

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k974465/>; 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 26, 2026