

K043295 VERSYO.DIRECTJan 5, 2005
37 days to decisionK043295 · Product code: **EBI** · Dental
Source: <https://www.510kdatabase.net/k043295/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Resin, Denture, Relining, Repairing, Rebasing (EBI)
Date received	Nov 29, 2004
Decision date	Jan 5, 2005
Days to decision	37 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Heraeus Kulzer, Inc.
Location	Elkhart, IN, US
Contact	CHERYL V ZIMMERMAN
510(k) history	145 submissions · 145 cleared · 1988-2009

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