

K974390 GLUMA ONE BONDFeb 4, 1998
75 days to decisionK974390 · Product code: **KLE** · Dental
Source: <https://www.510kdatabase.net/k974390/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agent, Tooth Bonding, Resin (KLE)
Date received	Nov 21, 1997
Decision date	Feb 4, 1998
Days to decision	75 days
Third-party review	No
Summary / Statement	Summary

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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