

**K964038 CHARISMA F, CHARISMA CREACTIVE, SOLID BOND,
& ESTICID -20FG**Apr 2, 1997
180 days to decisionK964038 · Product code: **KLE** · Dental
Source: <https://www.510kdatabase.net/k964038/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agent, Tooth Bonding, Resin (KLE)
Date received	Oct 4, 1996
Decision date	Apr 2, 1997
Days to decision	180 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k964038/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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