

K971733 2 BOND 2Oct 2, 1997
146 days to decisionK971733 · Product code: **KLE** · Dental
Source: <https://www.510kdatabase.net/k971733/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agent, Tooth Bonding, Resin (KLE)
Date received	May 9, 1997
Decision date	Oct 2, 1997
Days to decision	146 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k971733/> 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 May 20, 2026