

K200682 BZF-29Oct 2, 2020
200 days to decisionK200682 · Product code: **KLE** · Dental
Source: <https://www.510kdatabase.net/k200682/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agent, Tooth Bonding, Resin (KLE)
Date received	Mar 16, 2020
Decision date	Oct 2, 2020
Days to decision	200 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	GC America, Inc.
Location	Alsip, IL, US
Contact	Mark Heiss
510(k) history	125 submissions · 125 cleared · 1993-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k200682/> 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 14, 2026