

K180917 GC Acrylic PrimerNov 20, 2018
225 days to decisionK180917 · Product code: **KLE** · Dental
Source: <https://www.510kdatabase.net/k180917/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agent, Tooth Bonding, Resin (KLE)
Date received	Apr 9, 2018
Decision date	Nov 20, 2018
Days to decision	225 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	GC America, Inc.
Location	Alsip, IL, US
Contact	Mark Heiss
510(k) history	126 submissions · 126 cleared · 1993-2026

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