

K120521 GC BLUE SILICONEMay 10, 2012
79 days to decisionK120521 · Product code: **ELW** · Dental
Source: <https://www.510kdatabase.net/k120521/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Impression (ELW)
Date received	Feb 21, 2012
Decision date	May 10, 2012
Days to decision	79 days
Third-party review	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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