

**K181011 AIM2**Jul 12, 2018  
86 days to decisionK181011 · Product code: **ELW** · Dental  
Source: <https://www.510kdatabase.net/k181011/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Impression (ELW)
Date received	Apr 17, 2018
Decision date	Jul 12, 2018
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k181011/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 30, 2026