

**K973343 HYDROFLEX**Oct 21, 1997  
46 days to decisionK973343 · Product code: **ELW** · Dental  
Source: <https://www.510kdatabase.net/k973343/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Impression (ELW)
Date received	Sep 5, 1997
Decision date	Oct 21, 1997
Days to decision	46 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>GC America, Inc.</b>
Location	Alsip, IL, US
Contact	TERRY L JORITZ
510(k) history	126 submissions · 126 cleared · 1993-2026

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k973343/> 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 June 28, 2026