

**K090043 AUTOSURE VOICE BLOOD GLUCOSE MONITORING SYSTEM, MODEL AS90011F9**Apr 9, 2009  
92 days to decisionK090043 · Product code: **CGA** · Chemistry  
Source: <https://www.510kdatabase.net/k090043/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	Jan 7, 2009
Decision date	Apr 9, 2009
Days to decision	92 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Apex BioTechnology Corp.</b>
Location	Plymouth, MN, US
Contact	THOMAS Y.S. SHEN
510(k) history	35 submissions · 35 cleared · 2001-2025

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k090043/>; 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 23, 2026