

**K970664 GLUCOSE REAGENT**Aug 1, 1997  
161 days to decisionK970664 · Product code: **CFR** · Chemistry  
Source: <https://www.510kdatabase.net/k970664/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hexokinase, Glucose (CFR)
Date received	Feb 21, 1997
Decision date	Aug 1, 1997
Days to decision	161 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Derma Media Lab., Inc.</b>
Location	Santa Fe Springs, CA, US
Contact	CHARLES C ALLAIN, PH.D.
510(k) history	18 submissions · 18 cleared · 1996-1997

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k970664/> 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 30, 2026