

**K111452 PRESAGE ST2 ASSAY**Dec 9, 2011  
198 days to decisionK111452 · Product code: **OYG** · Chemistry  
Source: <https://www.510kdatabase.net/k111452/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	St2 Assay (OYG)
Date received	May 25, 2011
Decision date	Dec 9, 2011
Days to decision	198 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Critical Care Diagnostics, Inc. (Db a Critical Diag</b>
Location	San Diego, CA, US
Contact	JAMES SNIDER
510(k) history	1 submissions · 1 cleared · 2011-2011

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k111452/> 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 15, 2026