

**K943454 PLATO 3300/1300**Jan 9, 1995  
175 days to decisionK943454 · Product code: **JJQ** · Chemistry  
Source: <https://www.510kdatabase.net/k943454/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colorimeter, Photometer, Spectrophotometer For Clinical Use (JJQ)
Date received	Jul 18, 1994
Decision date	Jan 9, 1995
Days to decision	175 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Rosys, Inc.</b>
Location	Wilmington, DE, US
Contact	LEE CARTER
510(k) history	2 submissions · 2 cleared · 1994-1995

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k943454/> 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 July 1, 2026