

**K042723 TRIGAGE PROFILER S.O.B. PANEL, MODEL 97300**Dec 7, 2004  
67 days to decisionK042723 · Product code: **DAP** · Chemistry  
Source: <https://www.510kdatabase.net/k042723/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fibrinogen And Fibrin Split Products, Antigen, Antiserum, Control (DAP)
Date received	Oct 1, 2004
Decision date	Dec 7, 2004
Days to decision	67 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Biosite Incorporated</b>
Location	San Diego, CA, US
Contact	JERRREY R DAHLEN
510(k) history	46 submissions · 45 cleared · 1990-2010

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k042723/> 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 May 14, 2026