

**K914744 SYSMEX NE-1500, MODIFICATION**Dec 30, 1991  
69 days to decisionK914744 · Product code: **GKZ** · Hematology  
Source: <https://www.510kdatabase.net/k914744/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Oct 22, 1991
Decision date	Dec 30, 1991
Days to decision	69 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Toa Medical Electronics USA, Inc.</b>
Location	Mchenry, IL, US
Contact	NINA M GAMPERLING
510(k) history	33 submissions · 33 cleared · 1978-1994

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k914744/> 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 29, 2026