

**K970836 TRUCOUNT ABSOLUTE COUNT TUBES/COUNTING
CONTROL BEADS**Aug 26, 1997
183 days to decisionK970836 · Product code: **GKZ** · Hematology
Source: <https://www.510kdatabase.net/k970836/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Feb 24, 1997
Decision date	Aug 26, 1997
Days to decision	183 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Becton Dickinson Immunocytometry Systems
Location	San Jose, CA, US
Contact	ANNA LONGWELL
510(k) history	21 submissions · 21 cleared · 1989-2004

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k970836/> Data sourced from FDA 510(k) public records (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. - Generated June 28, 2026