FDA 510(k) Premarket Notification

K925909 GENESIS 1, AUTOMATED CELL COUNTER, MODIFICATION

CLEARED

Oct 27, 1994
723 days to decision

K925909 · Product code: **GKZ** · Hematology
Source: https://www.510kdatabase.net/k925909/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Nov 3, 1992
Decision date	Oct 27, 1994
Days to decision	723 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Alicia Diagnostics, Inc.**
Location	Oviedo, FL, US
Contact	JOHN T TOBIN
510(k) history	2 submissions · 2 cleared · 1991-1994