FDA 510(k) Premarket Notification

K910679 GENESIS I AUTOMATED CELL COUNTER

CLEARED

May 7, 1991
81 days to decision

K910679 · Product code: **GKL** · Hematology
Source: https://www.510kdatabase.net/k910679/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Cell, Automated (particle Counter) (GKL)
Date received	Feb 15, 1991
Decision date	May 7, 1991
Days to decision	81 days
Third-party review	No

APPLICANT

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