FDA 510(k) Premarket Notification

K802208 LEUKOCYTE VOL. ANALYSIS APPARATUS

CLEARED

Sep 17, 1980
6 days to decision

K802208 · Product code: **GKL** · Hematology
Source: https://www.510kdatabase.net/k802208/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Cell, Automated (particle Counter) (GKL)
Date received	Sep 11, 1980
Decision date	Sep 17, 1980
Days to decision	6 days
Third-party review	No

APPLICANT

Company	**Coulter Electronics, Inc.**
Location	Mchenry, IL, US
510(k) history	101 submissions · 101 cleared · 1976-1994