FDA 510(k) Premarket Notification

K833971 QUICK-COUNT

CLEARED

Jan 30, 1984
75 days to decision

K833971 · Product code: **GKL** · Hematology
Source: https://www.510kdatabase.net/k833971/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Cell, Automated (particle Counter) (GKL)
Date received	Nov 16, 1983
Decision date	Jan 30, 1984
Days to decision	75 days
Third-party review	No

APPLICANT

Company	**Seragen Diagnostics, Inc.**
Location	Mchenry, IL, US
510(k) history	20 submissions · 20 cleared · 1982-1987