FDA 510(k) Premarket Notification

K860586 PHA-2 CONVERSION PROGRAM FOR PLATELET ANALYSIS

CLEARED

May 7, 1986
77 days to decision

K860586 · Product code: **GKL** · Hematology
Source: https://www.510kdatabase.net/k860586/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Cell, Automated (particle Counter) (GKL)
Date received	Feb 19, 1986
Decision date	May 7, 1986
Days to decision	77 days
Third-party review	No

APPLICANT

Company	**Diagnostic Technology, Inc.**
Location	Mchenry, IL, US
Contact	ROBERT E LIND
510(k) history	28 submissions · 28 cleared · 1979-1991