FDA 510(k) Premarket Notification

K841803 A1 SYSTEME 8201/2

CLEARED

Feb 25, 1985
300 days to decision

K841803 · Product code: **GKL** · Hematology
Source: https://www.510kdatabase.net/k841803/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Cell, Automated (particle Counter) (GKL)
Date received	May 1, 1984
Decision date	Feb 25, 1985
Days to decision	300 days
Third-party review	No

APPLICANT

Company	**Med USA**
Location	Waltham, MA, US
Contact	JAMES R RUNDELL
510(k) history	5 submissions · 5 cleared · 1985-1990

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k841803/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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