

K822758 SYSMEX PDA-410 (PARTICLE DISTRIB. ANALYOct 18, 1982
34 days to decisionK822758 · Product code: **GKL** · Hematology
Source: <https://www.510kdatabase.net/k822758/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Cell, Automated (particle Counter) (GKL)
Date received	Sep 14, 1982
Decision date	Oct 18, 1982
Days to decision	34 days
Third-party review	No

APPLICANT

Company	Toa Medical Electronics USA, Inc.
Location	Mchenry, IL, US
510(k) history	33 submissions · 33 cleared · 1978-1994

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k822758/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 29, 2026