

K801357 MODIFIED BLOOD CELL COUNTING & LYSINGAug 14, 1980
66 days to decisionK801357 · Product code: **GIF** · Hematology
Source: <https://www.510kdatabase.net/k801357/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diluent, Blood Cell (GIF)
Date received	Jun 9, 1980
Decision date	Aug 14, 1980
Days to decision	66 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k801357/> 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 May 14, 2026