

K983203 IMMULITE EPO, MODEL #'S LKEPZ & LKEP1Jul 12, 1999
301 days to decisionK983203 · Product code: **GGT** · Hematology
Source: <https://www.510kdatabase.net/k983203/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Erythropoietin (GGT)
Date received	Sep 14, 1998
Decision date	Jul 12, 1999
Days to decision	301 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Diagnostic Products Corp.
Location	Mchenry, IL, US
Contact	EDWARD M LEVINE
510(k) history	321 submissions · 321 cleared · 1976-2006

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k983203/> 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 20, 2026