

**K894943 CLINIGEN ERYTHROPOIETIN HUMAN SERUM
CONTROLS 1,2,3**Oct 10, 1989
68 days to decisionK894943 · Product code: **GGT** · Hematology
Source: <https://www.510kdatabase.net/k894943/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Erythropoietin (GGT)
Date received	Aug 3, 1989
Decision date	Oct 10, 1989
Days to decision	68 days
Third-party review	No

APPLICANT

Company	Amgen, Inc.
Location	Thousand Oaks, CA, US
Contact	SARAH SWANSON
Website	http://www.amgen.com/
510(k) history	2 submissions · 2 cleared · 1988-1989

Amgen, Inc. is a worldwide pioneer in biotechnology with a manufacturing facility in Thousand Oaks, California. The company focuses on innovative therapies across multiple disease areas including oncology, cardiovascular health, bone health, and inflammation. Amgen received FDA 510(k) clearances from total submissions in the Hematology category. The company's regulatory record spans from 1988 to 1989. This represents a historical record of FDA device clearances; the company has not pursued additional 510(k) submissions in recent years. The cleared devices included erythro...
