FDA 510(k) Premarket Notification

K882686 ERYTHROPOIETIN ENZYME IMMUNOASSAY

CLEARED

Dec 20, 1988
173 days to decision

K882686 · Product code: **GGT** · Hematology
Source: https://www.510kdatabase.net/k882686/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Erythropoietin (GGT)
Date received	Jun 30, 1988
Decision date	Dec 20, 1988
Days to decision	173 days
Third-party review	No

APPLICANT

Company	**Amgen, Inc.**
Location	Thousand Oaks, CA, US
Contact	SARAH C 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...