

K895914 ABBOTT IMX IGENov 13, 1989
34 days to decisionK895914 · Product code: **DGC** · Immunology
Source: <https://www.510kdatabase.net/k895914/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ige, Antigen, Antiserum, Control (DGC)
Date received	Oct 10, 1989
Decision date	Nov 13, 1989
Days to decision	34 days
Third-party review	No

APPLICANT

Company	Abbott Laboratories
Location	Abbott Park, IL, US
Contact	JEAN FRYDMAN
Website	http://www.abbott.com
510(k) history	883 submissions · 868 cleared · 1976-2026

Abbott Laboratories is an American multinational medical devices and health care company headquartered in Abbott Park, Illinois. The company operates in over 160 countries and produces pharmaceuticals, diagnostics, nutritional products, and medical devices. Abbott maintains a substantial FDA 510(k) regulatory record with FDA 510(k) cleared devices from total submissions since 1976. The company's cleared devices span chemistry, microbiology, hematology, immunology, and toxicology categories. The latest clearance in 2025 reflects continued regulatory activity and product de...

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k895914/> 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 26, 2026