FDA 510(k) Premarket Notification

K893117 GLUCOMETER QA BLOOD GLUCOSE MTR/GLUCOFILM TEST ST

CLEARED

Jun 16, 1989
52 days to decision

K893117 · Product code: **CGA** · Chemistry
Source: https://www.510kdatabase.net/k893117/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	Apr 25, 1989
Decision date	Jun 16, 1989
Days to decision	52 days
Third-party review	No

APPLICANT

Company	**Bayer Corp.**
Location	Elkhart, IN, US
Contact	ROSANNE M SAVOL
510(k) history	96 submissions · 96 cleared · 1989-2003

Bayer Corp. is the American subsidiary of Bayer AG, headquartered in Whippany, New Jersey. The company operates 40 fully consolidated subsidiaries across 19 states. Bayer Corp. received FDA 510(k) clearances from total submissions, with no denied submissions on record. The company's regulatory activity spans from 1989 to 2003, with a primary focus on chemistry devices and immunology assays. Notable cleared devices include the ASCENSIA BREEZE BLOOD GLUCOSE METER, CLINITEST PREGNANCY TEST, and the ADVIA CENTAUR immunoassay system. This represents a historical regulatory rec...