FDA 510(k) Premarket Notification

K953939 QUINTEST

CLEARED

Nov 13, 1995
90 days to decision

K953939 · Product code: **SCL** · General Hospital
Source: https://www.510kdatabase.net/k953939/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Allergen And Vaccine Delivery Needles (SCL)
Date received	Aug 15, 1995
Decision date	Nov 13, 1995
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Bayer Corp.**
Location	Elkhart, IN, US
Contact	DAVID L MIRABELL
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...