FDA 510(k) Premarket Notification

K993353 TROPONIN I ASSAY FOR THE BAYER IMMUNO 1 SYSTEM (IN VITRO DIAGNOSTIC SYSTEM)

CLEARED

Dec 6, 1999
62 days to decision

K993353 · Product code: **MMI** · Chemistry
Source: https://www.510kdatabase.net/k993353/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunoassay Method, Troponin Subunit (MMI)
Date received	Oct 5, 1999
Decision date	Dec 6, 1999
Days to decision	62 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Bayer Corp.**
Location	Elkhart, IN, US
Contact	GABRIEL J MURACA JR
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...