FDA 510(k) Premarket Notification

K990449 HEMOCHRON ELECTRONIC SYSTEM VERIFICATION TUBE

CLEARED

Apr 13, 1999
60 days to decision

K990449 · Product code: **JPA** · Hematology
Source: https://www.510kdatabase.net/k990449/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Multipurpose For In Vitro Coagulation Studies (JPA)
Date received	Feb 12, 1999
Decision date	Apr 13, 1999
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**International Technidyne Corp.**
Location	Walker, MI, US
Contact	JOHN CLAY
510(k) history	47 submissions · 47 cleared · 1983-2013

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k990449/ 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 June 8, 2026