

**K010599 PROTOME MICROCOAGULATION SYSTEM / PROTOME
3 CUVETTE**Jul 2, 2001
124 days to decisionK010599 · Product code: **GJS** · Hematology
Source: <https://www.510kdatabase.net/k010599/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Test, Time, Prothrombin (GJS)
Date received	Feb 28, 2001
Decision date	Jul 2, 2001
Days to decision	124 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.netDevice record: <https://www.510kdatabase.net/k010599/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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