FDA 510(k) Premarket Notification

K010193 HEMOCHRON KAOLIN-ACTIVATED HEPARIN AND PROTAMINE DOSING ASSAYS

CLEARED

Jun 6, 2001
135 days to decision

K010193 · Product code: **KFF** · Hematology
Source: https://www.510kdatabase.net/k010193/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Heparin (KFF)
Date received	Jan 22, 2001
Decision date	Jun 6, 2001
Days to decision	135 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/k010193/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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