FDA 510(k) Premarket Notification

K061392 IKONISCOPE FASTFISH AUTO/AMNIOCYTE TEST SYSTEM

CLEARED

Aug 1, 2006
74 days to decision

K061392 · Product code: **JOY** · Hematology
Source: https://www.510kdatabase.net/k061392/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Automated Cell-locating (JOY)
Date received	May 19, 2006
Decision date	Aug 1, 2006
Days to decision	74 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ikonisys, Inc.**
Location	New Haven, CT, US
Contact	S. MICHAEL SHARP
510(k) history	4 submissions · 4 cleared · 2006-2008

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k061392/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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