FDA 510(k) Premarket Notification

K062755 IKONISCOPE ONCOFISH BLADDER TEST SYSTEM

CLEARED

Jan 4, 2007
112 days to decision

K062755 · Product code: **JOY** · Hematology
Source: https://www.510kdatabase.net/k062755/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Automated Cell-locating (JOY)
Date received	Sep 14, 2006
Decision date	Jan 4, 2007
Days to decision	112 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k062755/ 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 May 14, 2026