FDA 510(k) Premarket Notification

K994356 IMMUNOCYT

CLEARED

Feb 23, 2000
62 days to decision

K994356 · Product code: **NBK** · Pathology
Source: https://www.510kdatabase.net/k994356/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, (ihc), Tumor Marker, Monitoring, Bladder Cancer (NBK)
Date received	Dec 23, 1999
Decision date	Feb 23, 2000
Days to decision	62 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Diagnocure, Inc.**
Location	Washington, DC, US
Contact	BRUCE F MACKLER
510(k) history	1 submissions · 1 cleared · 2000-2000

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k994356/ 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