FDA 510(k) Premarket Notification

K022661 A1CNOW FOR HOME USE

CLEARED

Dec 13, 2002
126 days to decision

K022661 · Product code: **LCP** · Hematology
Source: https://www.510kdatabase.net/k022661/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Aug 9, 2002
Decision date	Dec 13, 2002
Days to decision	126 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Metrika, Inc.**
Location	Sunnyvale, CA, US
Contact	Erika B Ammirati
510(k) history	11 submissions · 11 cleared · 1999-2005