FDA 510(k) Premarket Notification

K011434 G7 AUTOMATED HPLC ANALYZER

CLEARED

Sep 18, 2001
131 days to decision

K011434 · Product code: **LCP** · Hematology
Source: https://www.510kdatabase.net/k011434/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	May 10, 2001
Decision date	Sep 18, 2001
Days to decision	131 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Tosoh Medics, Inc.**
Location	Washington, DC, US
Contact	LOIS NAKAYAMA
510(k) history	41 submissions · 41 cleared · 1990-2002