FDA 510(k) Premarket Notification

K972265 A1C 2.2 PLUS - AUTOMATED GLYCOHEMOGLOBIN ANALYZER

CLEARED

Sep 25, 1997
100 days to decision

K972265 · Product code: **LCP** · Hematology
Source: https://www.510kdatabase.net/k972265/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Jun 17, 1997
Decision date	Sep 25, 1997
Days to decision	100 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k972265/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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