FDA 510(k) Premarket Notification

K020489 G7 AUTOMATED HPLC ANALYZER, BETA-THALASSEMIA MODE

CLEARED

May 14, 2002
90 days to decision

K020489 · Product code: **JPD** · Hematology
Source: https://www.510kdatabase.net/k020489/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemoglobin A2 Quantitation (JPD)
Date received	Feb 13, 2002
Decision date	May 14, 2002
Days to decision	90 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