FDA 510(k) Premarket Notification

K923921 IL TEST PT FIBRINOGEN HS

CLEARED

Oct 26, 1992
82 days to decision

K923921 · Product code: **GIS** · Hematology
Source: https://www.510kdatabase.net/k923921/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Fibrinogen (GIS)
Date received	Aug 5, 1992
Decision date	Oct 26, 1992
Days to decision	82 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Instrumentation Laboratory CO**
Location	Mchenry, IL, US
Contact	WALLIS W CADY
510(k) history	321 submissions · 320 cleared · 1976-2023