FDA 510(k) Premarket Notification

K781880 ASSAY KIT, THROMBO-SCREEN

CLEARED

Dec 4, 1978
28 days to decision

K781880 · Product code: **GIS** · Hematology
Source: https://www.510kdatabase.net/k781880/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Fibrinogen (GIS)
Date received	Nov 6, 1978
Decision date	Dec 4, 1978
Days to decision	28 days
Third-party review	No

APPLICANT

Company	**Pacific Hemostasis**
Location	Mchenry, IL, US
510(k) history	29 submissions · 29 cleared · 1978-2000