FDA 510(k) Premarket Notification

K023362 FISHER DIAGNOSTICS THROMBOSCREEN 1000

CLEARED

Dec 9, 2002
63 days to decision

K023362 · Product code: **GKP** · Hematology
Source: https://www.510kdatabase.net/k023362/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Coagulation, Automated (GKP)
Date received	Oct 7, 2002
Decision date	Dec 9, 2002
Days to decision	63 days
Third-party review	No
Summary / Statement	Summary
Other names	PACIFIC HEMOSTASIS FIBRINOGEN REAGENT PLUS KAOLIN

APPLICANT

Company	**Fisher Diagnostics**
Location	Mchenry, IL, US
Contact	JERALD STEINER
510(k) history	16 submissions · 16 cleared · 1983-2017