FDA 510(k) Premarket Notification

K881685 FIBRINOGENTEST-O

CLEARED

Aug 9, 1988
112 days to decision

K881685 · Product code: **GIS** · Hematology
Source: https://www.510kdatabase.net/k881685/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Fibrinogen (GIS)
Date received	Apr 19, 1988
Decision date	Aug 9, 1988
Days to decision	112 days
Third-party review	No

APPLICANT

Company	**Diatech, Inc.**
Location	Mchenry, IL, US
Contact	L WILBOURN
510(k) history	17 submissions · 17 cleared · 1984-1988