FDA 510(k) Premarket Notification

K841461 COAGULATION CONTROL PLASMA LEVEL 1/2/3

CLEARED

May 2, 1984
23 days to decision

K841461 · Product code: **GGP** · Hematology
Source: https://www.510kdatabase.net/k841461/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Qualitative And Quantitative Factor Deficiency (GGP)
Date received	Apr 9, 1984
Decision date	May 2, 1984
Days to decision	23 days
Third-party review	No

APPLICANT

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