FDA 510(k) Premarket Notification

K820085 DADE FACTOR ASSAY REFERENCE PLASMA

CLEARED

Feb 23, 1982
42 days to decision

K820085 · Product code: **GGP** · Hematology
Source: https://www.510kdatabase.net/k820085/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Qualitative And Quantitative Factor Deficiency (GGP)
Date received	Jan 12, 1982
Decision date	Feb 23, 1982
Days to decision	42 days
Third-party review	No

APPLICANT

Company	**American Dade**
Location	Mchenry, IL, US
510(k) history	149 submissions · 149 cleared · 1980-1987