FDA 510(k) Premarket Notification

K882603 STACHROM ANTIPLASMIN CONTROL

CLEARED

Sep 2, 1988
70 days to decision

K882603 · Product code: **GGP** · Hematology
Source: https://www.510kdatabase.net/k882603/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Qualitative And Quantitative Factor Deficiency (GGP)
Date received	Jun 24, 1988
Decision date	Sep 2, 1988
Days to decision	70 days
Third-party review	No

APPLICANT

Company	**American Bioproducts Co.**
Location	Parsippany, NJ, US
Contact	LOC B LE,PHD
510(k) history	79 submissions · 75 cleared · 1985-1998