

K915163 PROTEIN S EID KIT AND PROTEIN S EID BULK PLATES

Jan 6, 1992
53 days to decision

K915163 · Product code: **GGP** · Hematology
Source: <https://www.510kdatabase.net/k915163/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Qualitative And Quantitative Factor Deficiency (GGP)
Date received	Nov 14, 1991
Decision date	Jan 6, 1992
Days to decision	53 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Biopool AB
Location	Ontario, L7I 6b8, CA
Contact	ANDREW L CERSKUS
510(k) history	13 submissions · 12 cleared · 1990-1995

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k915163/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026