

K934314 TINTELIZER(R) TPAFeb 23, 1994
175 days to decisionK934314 · Product code: **GGP** · Hematology
Source: <https://www.510kdatabase.net/k934314/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Qualitative And Quantitative Factor Deficiency (GGP)
Date received	Sep 1, 1993
Decision date	Feb 23, 1994
Days to decision	175 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

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