

K971219 CRYO CHECK INR VALIDATION SETAug 29, 1997
149 days to decisionK971219 · Product code: **GGN** · Hematology
Source: <https://www.510kdatabase.net/k971219/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plasma, Coagulation Control (GGN)
Date received	Apr 2, 1997
Decision date	Aug 29, 1997
Days to decision	149 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Precision Biologicals, Inc.
Location	Dartmouth, CA
Contact	STEPHEN L DUFF
510(k) history	20 submissions · 20 cleared · 1989-1999

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