

**K981752 I-STAT COAGULATION CONTROL SET**Jun 15, 1998  
28 days to decisionK981752 · Product code: **GGN** · Hematology  
Source: <https://www.510kdatabase.net/k981752/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plasma, Coagulation Control (GGN)
Date received	May 18, 1998
Decision date	Jun 15, 1998
Days to decision	28 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Biopool Intl., Inc.</b>
Location	Ventura, CA, US
Contact	MICHAEL D BICK
510(k) history	4 submissions · 4 cleared · 1998-2001

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k981752/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 28, 2026