

**K980314 FETAL D TECTION KIT**Apr 8, 1998  
71 days to decisionK980314 · Product code: **LIM** · Hematology  
Source: <https://www.510kdatabase.net/k980314/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Screening, For D Positive Fetal Rbc's (LIM)
Date received	Jan 27, 1998
Decision date	Apr 8, 1998
Days to decision	71 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k980314/> 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