FDA 510(k) Premarket Notification

K980314 FETAL D TECTION KIT

CLEARED

Apr 8, 1998
71 days to decision

K980314 · 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	**Biopool Intl., Inc.**
Location	Ventura, CA, US
Contact	PETER L MINETTI
510(k) history	4 submissions · 4 cleared · 1998-2001