FDA 510(k) Premarket Notification

K980331 IMMUNOSUPPRESSANT (WHOLE BLOOD) CONTROL, LEVEL 1 250-1, IMMUNOSUPPRESSANT (WHOLE BLOOS) CONTROL, LEVEL 2, 250-2, IMMUN\S

CLEARED

Mar 16, 1998
47 days to decision

K980331 · Product code: **DIF** · Toxicology
Source: https://www.510kdatabase.net/k980331/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drug Mixture Control Materials (DIF)
Date received	Jan 28, 1998
Decision date	Mar 16, 1998
Days to decision	47 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**More Diagnostics**
Location	Los Osos, CA, US
Contact	JAMES W SNIPES
510(k) history	16 submissions · 16 cleared · 1993-2008

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k980331/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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