FDA 510(k) Premarket Notification

K960471 TRI-COUNT 20

CLEARED

Mar 20, 1996
48 days to decision

K960471 · Product code: **JPK** · Hematology
Source: https://www.510kdatabase.net/k960471/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mixture, Hematology Quality Control (JPK)
Date received	Feb 1, 1996
Decision date	Mar 20, 1996
Days to decision	48 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Hematronix, Inc.**
Location	Plano, TX, US
Contact	JAMES D LAPICOLA
510(k) history	9 submissions · 9 cleared · 1990-2001