FDA 510(k) Premarket Notification

K913467 TOXOGEN

CLEARED

Jan 11, 1993
525 days to decision

K913467 · Product code: **LLA** · Microbiology
Source: https://www.510kdatabase.net/k913467/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Direct Agglutination Test, Toxoplasma Gondii (LLA)
Date received	Aug 5, 1991
Decision date	Jan 11, 1993
Days to decision	525 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Biokit USA, Inc.**
Location	Mchenry, IL, US
Contact	ODRIOZOLA
510(k) history	16 submissions · 16 cleared · 1984-1993