FDA 510(k) Premarket Notification

K894946 PLATELIA RUBELLA IGG KIT

CLEARED

Dec 21, 1989
140 days to decision

K894946 · Product code: **LFX** · Microbiology
Source: https://www.510kdatabase.net/k894946/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Rubella (LFX)
Date received	Aug 3, 1989
Decision date	Dec 21, 1989
Days to decision	140 days
Third-party review	No

APPLICANT

Company	**Kallestad Diag, A Div. of Erbamont, Inc.**
Location	Chaska, MN, US
Contact	SUSAN TESMER
510(k) history	58 submissions · 58 cleared · 1987-1991