FDA 510(k) Premarket Notification

K072617 ELECSYS RUBELLA IGG IMMUNOASSAY

CLEARED

Dec 5, 2008
445 days to decision

K072617 · Product code: **LFX** · Microbiology
Source: https://www.510kdatabase.net/k072617/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Rubella (LFX)
Date received	Sep 17, 2007
Decision date	Dec 5, 2008
Days to decision	445 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Roche Diagnostics Corp.**
Location	Indianapolis, IN, US
Contact	THERESA A BUSH
510(k) history	264 submissions · 263 cleared · 1999-2013