FDA 510(k) Premarket Notification

K013128 N LATEX LP(A)

CLEARED

Jan 18, 2002
121 days to decision

K013128 · Product code: **DFC** · Chemistry
Source: https://www.510kdatabase.net/k013128/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lipoprotein, Low-density, Antigen, Antiserum, Control (DFC)
Date received	Sep 19, 2001
Decision date	Jan 18, 2002
Days to decision	121 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Dade Behring, Inc.**
Location	Newark,, DE, US
Contact	REBECCA S AYASH
510(k) history	343 submissions · 343 cleared · 1978-2010