

K013128 N LATEX LP(A)Jan 18, 2002
121 days to decisionK013128 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k013128/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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