

**K001118 MODIFICATION TO LIPOPROTEIN (A) SPQ III
ANTIBODY REAGENT SET**Apr 25, 2000
18 days to decisionK001118 · Product code: **DFC** · Chemistry
Source: <https://www.510kdatabase.net/k001118/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Lipoprotein, Low-density, Antigen, Antiserum, Control (DFC)
Date received	Apr 7, 2000
Decision date	Apr 25, 2000
Days to decision	18 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	DiaSorin, Inc.
Location	Ellicott City, MD, US
Contact	JUDITH J SMITH
510(k) history	71 submissions · 70 cleared · 1998-2026

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