

K885048 ACCESS R-CLONE ANA PROFILE ASSAYJan 24, 1989
48 days to decisionK885048 · Product code: **DHC** · Immunology
Source: <https://www.510kdatabase.net/k885048/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Systemic Lupus Erythematosus (DHC)
Date received	Dec 7, 1988
Decision date	Jan 24, 1989
Days to decision	48 days
Third-party review	No

APPLICANT

Company	Lipogen, Inc.
Location	Knoxville, TN, US
Contact	DEES, PH.D.
510(k) history	15 submissions · 15 cleared · 1987-1990

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