

K894894 ANTI-SM MICROASSAYAug 24, 1989
23 days to decisionK894894 · Product code: **LJM** · Immunology
Source: <https://www.510kdatabase.net/k894894/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody (enzyme-labeled), Antigen, Controls (LJM)
Date received	Aug 1, 1989
Decision date	Aug 24, 1989
Days to decision	23 days
Third-party review	No

APPLICANT

Company	Diamedix Corp.
Location	Miami, FL, US
Contact	DAVID J KIEFER,PHD
510(k) history	68 submissions · 68 cleared · 1986-2011

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