

**K940229 SYN ENA SCREEN (PIN PLATE)**May 11, 1994  
113 days to decisionK940229 · Product code: LLL · Immunology  
Source: <https://www.510kdatabase.net/k940229/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Extractable Antinuclear Antibody, Antigen And Control (LLL)
Date received	Jan 18, 1994
Decision date	May 11, 1994
Days to decision	113 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Elias U.S.A., Inc.</b>
Location	Osceola, WI, US
Contact	GOTTFRIED KELLERMANN,PH.D
510(k) history	54 submissions · 54 cleared · 1992-1997

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