

K 955603



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* 510(k) SUMMARY *

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Name of Device:

- Trade Name - RELISA® SS-A/Ro and SS-B/La Antibody Test System
- Common Name - SS-A/Ro and SS-B/La Antibody Test System
- Classification Name - Extractable Antinuclear Antibody (21 CFR 866.5100)

Legally marketed device with which this device has been shown to be equivalent:

RELISA® ENA Antibody Screening Tests System, K935129

Description:

This is an enzyme immunoassay for the detection of antibodies to nuclear antigens SS-A/Ro and SS-B/La in human serum.

Intended Use:

This test system is for in vitro diagnostic use for the detection of antibodies to nuclear antigens SS-A/Ro and SS-B/La in human serum.

Summary of Technological Characteristics Compared to the Predicate Device:

This device is identical to the predicate device with the following exceptions:

- a) The predicate device has six different autoantigens coated on individual microwells; the present device has only SS-A/Ro or SS-B/La autoantigen coated on the microwells.
- b) The predicate device includes a procedure control well on each strip of microwells, the present device includes a calibrator serum in the kit.

Description of Laboratory Data That Indicate Substantial Equivalence:

For direct determination of relative sensitivity and specificity, we used the Immuno Concepts RELISA® Screening Assay (K935129) as a reference method. The data obtained in this comparison are shown in the following Tables.

Table 1. Detection of antibodies to the SS-A(Ro) autoantigen.

		Immuno Concepts Positive	RELISA® Borderline	Screening Assay Negative
Immuno Concepts RELISA® SS-A/SS-B	Positive	62	0	0
	Borderline	0	2	0
	Negative	0	0	96

These data yield the following statistics: relative sensitivity, 100.0%; relative specificity, 100.0%; and overall agreement, 100.0%

Table 2. Detection of antibodies to the SS-B(La) autoantigen.

		Immuno Concepts Positive	RELISA® Borderline	Screening Assay Negative
Immuno Concepts RELISA® SS-A/SS-B	Positive	32	2	0
	Borderline	0	5	0
	Negative	0	0	121

The two samples that gave borderline positive results with the screening assay and positive results with the SS-B(La) specific assay are considered positive samples. These data yield the following statistics: relative sensitivity, 100.0%; relative specificity, 100.0%; and overall agreement, 100.0%

In accordance with 21 CFR 807.92(b)(3), we conclude from these data that the present device is substantially equivalent to the predicate device.