K955602

immuno concepts

APR 19 1996

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* 510(k) SUMMARY *
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Date Prepared: December 4, 1995
Contact Person: Eric S. Hoy, Ph.D.
Name of Device:

- Trade Name - RELISA® Scl-70 Antibody Test System
- Common Name - Scl-70 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 antigen Scl-70 in human serum.

Intended Use:

This test system is for in vitro diagnostic use for the detection of antibodies to nuclear antigen Scl-70 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 Scl-70 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 specificty, we used the Immuno Concepts RELISA® Screening Assay (K935129) as a reference method. The data obtained in this comparison are shown in the following Table.

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Table 1. Detection of antibodies to the Scl-70 autoantigen.

		Immuno Concepts RELISA® Screening Assay		
		Positive	Borderline	Negative
Immuno Concepts RELISA® Scl-70	Positive	37	3	0
	Borderline	0	7	0
	Negative	0	1	129

If we assume that "borderline" results are actually positive, these data yield the following statistics: relative sensitivity, 97.9%; relative specificity, 100%; and overall agreement, 99.4%

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.