K971282

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AUG 28 1997

510(k) Summary

1. Submitter's Name/Contact Person

Joseph M. Califano Manager, Regulatory Affairs

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Date Prepared

25 July 1997

2. Device Name

Trade Name:	Prealbumin SPIA ™
Common Name:	Prealbumin
Classification Name:	System, Test, immunological, prealbumin

3. Predicate Device

Incstar Antibody Reagent Set II for Prealbumin
{510 (k) Docket No. K 884297}

3a. Methods

Manual method:	Described in Immunoturbidimetry of transthyretin (prealbumin) in human sera. Clin. Chem: **33:** 7, 1260 1987. Ledue T.B., Rifai N, Irish, G.R., Silverman, L.M.
Automated System:	COBAS-MIRA Analyzer. **{510 (k) Docket No. K 851172}**

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4. Description of Device

Raichem's Prealbumin SPIA ™ is a quantitative turbidimetric assay for the detection and measurement of prealbumin in human serum and plasma. The assay has been standardized to a CAP Reference Preparation. The assay reagents consist of a polymer diluent, a polyclonal antibody to human prealbumin, calibrators, and controls.

In this assay, a complex forms between the prealbumin, and anti-prealbumin antibodies causing turbidity. The change in optical density is proportional to the amount of prealbumin present. A quantitative determination of the amount of prealbumin present in a serum/plasma sample is made by comparison to a standard curve.

5. Intended Use of Device

The Prealbumin SPIA™ is a quantitative turbidimetric assay intended for the detection of prealbumin levels in human serum and plasma. Measurement of prealbumin levels may aid in the assessment of an individual's nutritional status.

6.(A) Technological Characteristics

Proposed Device

Raichem's Prealbumin SPIA ™ is a quantitative turbidimetric assay. This assay is performed manually following clinically accepted methodologies. The assay is designed to enable users to readily adapt it for use with automated systems such as the Roche COBAS MIRA Analyzer.

Predicate Device

Incstar's Antibody Reagent Set II for Prealbumin is also a quantitative turbidimetric assay that utilizes immunoprecipitin analysis for the determination of prealbumin levels.

6.(B) Performance Data

I. Precision

To evaluate precision, inter-assay and intra-assay studies were conducted with the **Raichem's Prealbumin SPIA ™** on an automated system {COBAS-MIRA}

A. Inter-assay reproducibility

Eight different serum samples were assayed ten times over six different days.

SAMPLE	Mean mg/dL	Std. Dev	% CV	Mean Delta	Std. Dev	% CV
1	36.3	1.9	5.2	0.272	0.007	2.7
2	17.1	1.1	6.6	0.188	0.007	3.5
3	7.7	0.4	5.6	0.115	0.004	3.3
4	14.1	0.9	6.4	0.168	0.006	3.7
5	22.3	1.1	4.8	0.217	0.004	1.9
6	26.3	1.2	4.7	0.237	0.004	1.9
7	36.7	2.5	6.7	0.273	0.008	2.9
8	50.4	2.5	4.9	0.305	0.007	2.2

B. Intra-assay reproducibility

The eight serum samples were also assayed 20 consecutive times in a single run.

SAMPLE	Mean mg/dL	Std. Dev	% CV	Mean Delta	Std. Dev	% CV
1	34.3	1.6	4.8	0.280	0.006	2.2
2	17.4	0.7	4.1	0.195	0.003	1.7
3	8.0	0.2	2.6	0.114	0.002	1.8
4	13.7	0.8	5.7	0.159	0.006	3.7
5	22.7	0.6	2.5	0.214	0.003	1.4
6	28.6	1.0	3.6	0.240	0.004	1.7
7	34.7	1.4	4.0	0.263	0.005	1.8
8	50.7	2.7	5.3	0.304	0.006	1.8

II. Standardization of the Calibrators

The set of 5 calibrators supplied with the assay have been standardized within the dynamic range { 0 to 55 mg/dL} using the College of American Pathologists Reference Preparation for Proteins in Human Serum, Catalog Number RM002.

III. Assay Sensitivity

The detection limit of the assay was determined by running multiple replicates the 0 mg/dL Calibrator and computing the mean and standard deviation. The resultant detection limit was found to be 0.9 mg/dL. {Mean + 2SD}

IV. **Comparison Studies**

a. The **Prealbumin SPIA ™** and the **Incstar Antibody Reagent Set II for Prealbumin** were used to assay serum specimens from individuals being screened for prealbumin levels and apparently healthy blood donors. The specimens were assayed concurrently with both the proposed and predicate devices, using an automated method {COBAS-MIRA}

A total of 134 samples were evaluated. The results indicated a high degree of linear correlation between the proposed and predicate device. The resultant linear regression relationship is:

$$Y_{PROPOSED} = 1.06\ X_{PREDICATE} - 1.15, \quad r^2 = 0.932$$

b. **Comparison of a manual method and an automated method{COBAS-MIRA}**

The **Raichem Prealbumin SPIA ™** was used to assay serum specimens concurrently by a manual method and an automated method {COBAS-MIRA}

A total of 30 samples were evaluated. The results indicated a high degree of linear correlation between the manual and automated methods. The resultant linear regression relationship is:

$$Y_{AUTOMATED} = 1.10\ X_{MANUAL} + 1.07, \quad r^2 = 0.959$$

V **Assay performance with Serum and Plasma**

Twenty five (25) matched serum and EDTA-plasma samples were compared. Half of the volume of each sample was converted to serum by recalcification using a standard Ca^{2+}/thrombin methodology. Each of the plasma and converted serum samples were evaluated with the proposed device on an automated system {COBAS-MIRA}. The results of the evaluation with the proposed device indicate that it can provide accurate estimates of prealbumin levels in both human serum and EDTA-plasma.

VI. **Interfering Substances**

Lipemic, hemolytic, and icteric samples were evaluated with the assay. The results indicate that there is no significant effect (< 20 % variation) on the assay for samples with:

Hemoglobin concentration:	≤ 500 mg/dL
Bilirubin concentration:	≤ 20 mg/dL

Lipid concentrations of > 200 mg/dL showed significant decreases in prealbumin values.

7. ***Conclusion***

The results of the comparative studies support the claim that the **Prealbumin SPIA ™** is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 28 1997

Mr. Joseph M. Califano
Manager, Regulatory Affairs
Hemagen Diagnostics, Inc.
34-40 Bear Hill Road
Waltham, Massachusetts 02154

Re: K972812
Trade Name: Prealbumin SPIA™
Regulatory Class: I
Product Code: DDS
Dated: July 25, 1997
Received: July 28, 1997

Dear Mr. Califano:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html"

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Device Name: **Prealbumin SPIA ™**

Indication(s) For Use

The use of these reagents is indicated for the measurement of prealbumin levels in human serum or plasma.

(PLEASE DO NOT WRITE BELOW THIS LINE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use ___
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number