

JUN 15 1998

K981496



A Subsidiary of
Mitsubishi Chemical Corporation

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www.seradyn.com

510(k) Summary
[As Required by 21 CFR 807.92 (c)]

1. Company/contact person:

Seradyn, Inc.
1200 Madison Avenue
Indianapolis, IN 46225

Establishment registration No: 1819246

Martin J. Weinstein
Vice President, Manufacturing and Regulatory Affairs
Telephone: (317) 266-2941
Fax: (317) 266-2991

2. Prepared:

April 24, 1998

3. Device Name:

- a. Proprietary Name: ColorSlide® RF
- b. Common Name: Rheumatoid Factors (RF), Latex Agglutination Test
- c. Classification Name: Rheumatoid Factor, System, Test

4. Legally marketed devices to which equivalency is claimed:

Seradyn ColorSlide® RF is substantially equivalent to both Seradyn's SeraTest™ RF and Behring's Rapitex RF.

5. Description of Device:

ColorSlide® RF is a rapid latex particle agglutination assay for the determination of circulating Rheumatoid Factors (RF) in human serum.

6. Intended Use:

The test provides qualitative and semi-quantitative determination of rheumatoid factors (RF) in human serum. The test provides results for one of the seven criteria used in the diagnosis of rheumatoid arthritis as suggested by the American College of Rheumatology

7. Comparison of Technological Characteristics:

Both ColorSlide® RF and SeraTest™ RF are non-automated manual tests employing latex particles coated with human IgG as the solid phase matrix. As such, both systems have similar technological characteristics. There are no major differences in technology. The agglutination reaction (or the absence thereof) in both cases is read visually. Like SeraTest™ RF, ColorSlide® RF is intended as a screening test for rheumatoid factors. Both latex tests can be used semi-quantitatively for the determination of circulating rheumatoid factors in human serum.

Differences between the two assays are listed in the following table:

ColorSlide® RF	SeraTest™ RF
Human IgG is covalently coupled to the particle.	Human IgG is absorbed by the particle (process change).
Latex particle has been dyed blue.	The latex particle is naturally white.
Requires no retesting to confirm positive samples.	Requires that all positive samples be confirmed at a 1:20 dilution.

8. Summary of Non-clinical Testing:

NONE

9. Summary of Clinical Testing:

A. Comparison to SeraTest™ RF

Testing was conducted at one site. A total of 103 patient samples were tested by both ColorSlide® RF and SeraTest™ RF.

Qualitative Assay:

The results of the qualitative procedure are summarized in the following table. An acceptable correlation was obtained between the two tests.

	ColorSlide RF +	ColorSlide RF -	Total
SeraTest™ RF +	55	0	55
SeraTest™ RF -	1	47	48
Total	56	47	103

Relative Sensitivity:	100%
Relative Specificity:	97.9%
Positive Predictive Value:	98.2%
Negative Predictive Value:	100%
Efficiency of Test:	99.03%

Semi-Quantitative Assay:

The titers of the 133 positive samples were determined. An acceptable correlation was obtained between the two tests. The results are summarized in the following table.

Agreement	Number of Samples	Percentage
Complete	16	28.6%
+/- One Dilution	31	55.4%
> One Dilution	9	16.1%
Total	56	

B. Comparison to Behring's

Testing was conducted at three sites. A total of 309 patient samples were tested by both ColorSlide® RF and RapiTex RF.

Qualitative Assay:

The results of the qualitative procedure are summarized in the following table. An acceptable correlation was obtained between the two tests.

	ColorSlide RF +	ColorSlide RF -	Total
RapiTex RF +	127	3	130
RapiTex RF -	3	176	179
Total	130	179	309

Relative Sensitivity:	97.69%
Relative Specificity:	98.32%
Positive Predictive Value:	97.69%
Negative Predictive Value:	98.32%
Efficiency of Test:	98.06%

Semi-Quantitative Assay:

The titers of the 133 positive samples were determined. An acceptable correlation was obtained between the two tests. The results are summarized in the following table.

Agreement	Number of Samples	Percentage
Complete	63	47.37%
+/- One Dilution	64	48.12%
> One Dilution	6	4.5%
Total	133	

C. Lot-to-Lot Comparison Study

The reproducibility of three lots made on different days was compared. A panel of 6 patients serum (3 positive and 3 negative) was assayed with all three lots. Positive controls and positive serum were titered to an end point.

Kits from all three lots performed satisfactorily with little or no lot-to-lot variability. All titers fell within one doubling dilution.

D. Sensitivity based on an international standard

Sensitivity based on the first British Standard (64/2) for Rheumatoid Arthritis Serum (traceable to a WHO reference serum) was approximately 20 IU/mL.

E. Passive Interference Study

Hemoglobin (at 1,000 mg/dL), or bilirubin (at 40 mg/dL) or lipid (at 20 g/L) in serum did not adversely interfere with the assay.

F. Stability Data

Current stability data for SeraTest™ RF goes out beyond 15 months.

One development lot of ColorSlide® RF was monitored for approximately 400 days. Performance was within specifications.

Three stability studies are currently in progress. The product is being stored in accordance with label copy. These studies will be continued for at least two years.

Product expiration dating will be based on data available to Seradyn at the time of manufacture.

10. Conclusions:

The results of clinical testing demonstrate that the performance and effectiveness of the ColorSlide® RF test are substantially equivalent to those of Seradyn's SeraTest™ RF and Behring's RapiTex RF.

11. Other Information:

None



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN 15 1998

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Martin J. Weinstein
Vice President, Manufacturing and
Regulatory Affairs
Seradyn, Inc.
1200 Madison Avenue
Indianapolis, Indiana 46225

Re: K981496
Trade Name: ColorSlide® RF
Regulatory Class: II
Product Code: DHR
Dated: April 24, 1998
Received: April 27, 1998

Dear Mr. Weinstein:

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.

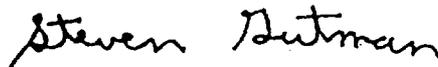
Page 2

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

Enclosure

510(k) Number (if known): K981496

Device Name: ColorSlide[®] RF

Indications For Use:

The test provides qualitative and semi-quantitative determination of rheumatoid factors (RF) in human serum. The test provides results for one of the seven criteria used in the diagnosis of rheumatoid arthritis as suggested by the American College of Rheumatology



(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)