

4/21/99

K990206 Page 1 of 3



P.O. Box 4002, Elkhart, IN 46514-0002 • (219) 264-3440 • FAX (219) 266-6222

RECEIVED  
JAN 21 4 23 PM '99  
FDA/CDRH/ODE/DMC

## 510(k) SUMMARY

Serim™ Blood Leak Test Strips

**Submitted by:**

Robert J. Carrico  
Serim Research Corporation  
P.O. Box 4002  
Elkhart, IN 46514

Phone: (219) 264-3440  
Fax: (219) 266-6222

Contact person: Robert J. Carrico

Date prepared: January 19, 1999

*Robert J. Carrico  
Jan 19, 1999*

**Device Name:**

Trade name: SERIM™ Blood Leak Test Strips  
Common name: Occult blood test strip

Classification name: Dialysis Blood Leak Test

**Legally Marketed Equivalent Device:**

This product is similar in design, composition and function to the occult blood test pad on Chemstrip 10 urine test strip manufactured by Boehringer Mannheim Corporation which was the subject of Premarket Notification #K896454. The product is similar in utility to the cyanomethemoglobin assay. Supportive data for substantial equivalence to the latter was obtained.

**Description of the SERIM™ Blood Leak Test Strip**

*SK-58*

The SERIM Blood Leak Test Strip consists of a 0.2 x 0.2 inch reagent pad attached to one end of a white 0.2 x 3.25 inch polystyrene handle. The reagent pad is immersed into a sample, removed immediately and allowed to react for 60 seconds. Then the reagent pad color is compared to two color blocks on the bottle label. One color block marked Negative is yellow with a few green speckles. If a reagent pad has a similar yellow color the dialysate does not contain significant blood. The second color block is green with small yellow speckles and is marked Positive. A reagent pad with green color equal to or darker than this color block indicates the presence of a significant blood leak.

The Association for the Advancement of Medical Instrumentation(AAMI) standards recommend that blood loss be limited to 0.35 mL/minute or less. This calculates to 5.5 mg/dL hemoglobin at 25% hematocrit. (AAMI Standards and Recommended Practices, Vol. 3, 1998, p. 57) SERIM Blood Leak Test Strips are designed to give a positive readings with 1.5 mg/dL hemoglobin in acid/bicarbonate buffer, pH 7.4. Thus, a positive test strip reading corresponds to approximately 0.1 mL/minute blood loss.

#### **Intended Use:**

Hemodialyzers are equipped with photometric sensors in the dialysate stream to detect blood leaks at the dialysis membranes. The sensors measure red color in the dialysate due to hemoglobin in red blood cells. Sensors are calibrated to sound an alarm when blood loss reaches 0.35 mL/minute.

A confirmed blood leak requires termination of the dialysis session and restarting the dialysis with a new dialyzer. Occasionally false alarms occur possibly due to gas bubbles in the sensor. Since interrupting a dialysis session is stressful for the patient, technicians prefer to confirm an alarm before taking further steps. SERIM Blood Leak Test Strips provide a quick and convenient means to test for occult blood in hemodialysis fluids.

#### **Technological Comparison to Predicate Device:**

SERIM Blood Leak Test Strips and Chemstrip occult blood test both utilize the peroxidase-like activity of hemoglobin to detect whole blood in fluids. Both tests have an organic peroxide and a chromogen dried in test pads. When the pads are exposed to test samples the organic peroxide and chromogen react extremely slowly unless hemoglobin from red blood cells is present. Hemoglobin catalyzes the oxidation of the chromogen to produce green color. The rate of color formation is dependent on the concentration of hemoglobin in the test sample. In some applications the level of occult blood in samples is estimated from the amount of color produced. However, a positive/negative answer is preferable in the hemodialysis application. SERIM Blood Leak Test Strips have adequate sensitivity to detect hemoglobin at the required levels as discussed above. Two color blocks used in the test provide a clear distinction between Positive and Negative readings. If a reading between the two blocks is obtained a very small leak may be

present and dialysis can be continued because the leak can seal.

#### **Statement of Substantial Equivalence**

SERIM Blood Leak Test Strips from two production lots were used by 12 participants to test blood standards in blind studies. One hundred negative strip readings (100% specificity) were obtained with dialysis buffer without blood. One hundred positive strip readings (100% sensitivity) were obtained with dialysis buffer containing non-hemolyzed blood at 1.5 mg/dL hemoglobin, determined by the cyanmethemoglobin method.

SERIM Blood Leak Test Strips and Chemstrip occult blood strips (the test for which equivalence is claimed) were used to test 101 dialysates collected at a dialysis clinic. Negative readings for blood leaks were obtained with both tests. Non-hemolyzed blood was added to thirty-three of the dialysate samples to give 1.5 mg/dL hemoglobin. The spiked samples all gave positive blood leak readings with both types of strips.



APR 21 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850Robert J. Carrico, Ph.D.  
Staff Scientist  
Serim Research Corporation  
P.O. Box 4002  
Elkhart, IN 46514-0002Re: K990206  
Serim™ Blood Leak Test Strips  
Dated: January 19, 1999  
Received: January 21, 1999  
Regulatory Class: II  
21 CFR 876.5820/Procode: 78 FJD

Dear Dr. Carrico:

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 legally marketed predicate 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 requirements, 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.

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) 594-4613. 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 (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.  
Acting Director, Division of Reproductive,  
Abdominal, Ear, Nose and Throat,  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): K990206

Device Name: Serim Blood Leak Test Strips

Indications For Use:

SERIM Blood Leak Test Strips provide a rapid and convenient means for testing spent dialysate for blood in hemodialysis clinics. The presence of blood in dialysate indicates a leak in the dialysis membrane.

(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)

David G. Segrum  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K990206