JUN 13 2005

510 (K) SUMMARY

Prepared: May 20, 2005

Submitter: SERIM Research Corporation

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Contact: Patricia A. Rupchock
Manager of Regulatory Affairs

Device:

Trade/Proprietary Name: SERIM™ Dialysate Monitor™ Test Strip

Common/ Usual Name: Test for pH in dialysate
Test for glucose as tracer for acid concentrate in dialysate
Test for bicarbonate in dialysate

Device Classification Name: Strip, Dialysate, pH, bicarbonate, glucose, acid, indicator

Medical Specialty: GU

Product Code: NTZ

Class: II

Regulation Number: 876.5820

Predicate Devices:

SERIM™ Dialysate Monitor™ Test Pad	Legally marketed device
Test for pH in dialysate **Previously cleared – no significant modifications which affect safety or effectiveness or impacts the indications for use.**	K945491
Test for glucose as tracer for acid concentrate in dialysate	Bayer Multistix® 10SG (glucose pad) K992257
Test for bicarbonate in dialysate	IBP Gmbh Model HDM97 conductivity meter 510(k) number K020908

Device Description:

SERIM Dialysate Monitor Test Strips are firm plastic strips that contain three reagent areas to test for pH, bicarbonate/carbonate ion, and glucose in dialysate. The glucose concentration is a tracer of the amount of acid concentrate added to the dialysate.

Intended Use:

The Serim Dialysate Monitor Test Strips provide semi-quantitative indications of pH, bicarbonate ion, and glucose in the final bicarbonate dialysate.

SERIM™ Dialysate Monitor™ Test Strips determine whether dialysate concentrates for hemodialysis were diluted properly to give a final dialysate with the proper proportions of bicarbonate and acetic acid/glucose. Significant misdilutions of the acid concentrate will give rise to excessively high and low levels of pH, alkalinity, and glucose in the dialysate The test is intended to supplement current methods of dialysate testing.

Technological Characteristics:

The characteristics of each pad on the test strip will be compared with its individual predicate device. The pH strip is identical to that which has been previously cleared by the FDA (K945491). In this submission, the pH readings of the strip were compared to that of pH meters using glass electrodes.

The bicarbonate test pad is based on the neutralization of a weak

acid incorporated into the test pad. This process will cause a change in the ratio of acid and salt form of the acid that in turn leads to a pH change in the buffer system. This pH change produces a visual change in the color of a pH indicator in the pad. This color change can be correlated with the concentration of bicarbonate originally present in the sample. The predicate device is a conductivity meter. These are routinely used in dialysis as a measurement of the conductivity of the final dialysate solution. We have specifically used as the predicate device, an IBP HDM97 conductivity meter, (510(k) number K020908).

Conductivity is a function of the concentration of all ionic material in the test solution and of the mobility of the individual ions, with hydrogen ion being especially mobile. As the concentration of bicarbonate in the final dialysate changes due to misdilution, the conductivity of the solution correlates with changing bicarbonate concentration. Therefore, we expect and we have found that the color of the test strip also correlates with bicarbonate concentration. Since both the conductivity and the test strip colors correlate with total ionic concentrations it was expected and was found experimentally that the test strips correlated well with the conductivity of the final dialysate assuming that the concentration of other ions remains about constant.

Generally, glucose (a.k.a. dextrose) is added routinely to dialysis solutions for all patients in quantities sufficient to insure that, when properly diluted, the resulting glucose concentration should be 200 mg/dl. (0.2%). The constant level of glucose in these solutions is included by the manufacturer with the acetic acid concentrate. Therefore, the glucose can act as a tracer for the acid concentrate.

The glucose test strip used in this test is similar in composition to the predicate device. It consists of glucose oxidase, peroxidase, buffers, and an indicator. We compared the performance of the Serim glucose test strip against the performance of the glucose pad on the Bayer MultiStix 10 SG test strip using standard glucose solutions prepared in dialysate. For simplicity, the glucose pad on the Bayer MultiStix 10 SG test strip will be referred to as the Bayer glucose strip. Each test strip separately correlated well with known glucose concentrations. Therefore, it was expected and found that the Serim test strip correlated well

with the predicate Bayer test strip.

Performance: The performance of the SERIM Dialysate Monitor Test Strips was studied using samples obtained from a dialysis clinic. In addition, normal and intentionally misdiluted samples were prepared. Significantly misdiluted samples had intentional dilution errors of 2X or 0.5X the correct amount of bicarbonate concentrate. All normal samples gave the expected values as read by the test strips. Significantly misdiluted samples were readily detected by the strips and also provided indications of which component, acid or bicarbonate concentrate was added in the improper amount. We have shown that when solutions were misdiluted by 35% or more, there was a good probability of detecting this misdilution by means of the test strip. Each of the pads on the test strips was substantially equivalent to the results of the corresponding predicate devices.

Conclusion: These studies indicate that SERIM Dialysate Monitor Test Strips can be used to monitor the proportioning of sodium bicarbonate, acid concentrate and purified water to determine that the final mix is appropriately prepared. These strips are to be used to supplement current dialysate testing regimens.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 13 2005

Ms. Patricia Rupchock
Manager of Regulatory Affairs
Serim Research Corporation
23565 Reedy Drive
ELKHART IN 46514

Re: K043031
Trade/Device Name: SERIM™ Dialysate™ Monitor™ Test Strip
Regulation Number: 21 CFR §876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Codes: NTZ
Dated: January 19, 2005
Received: January 21, 2005

Dear Ms. Rupchock:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K043031

Device Name: Serim™ Dialysate Monitor™ Test Strip

Indications for Use:

The Serim™ Dialysate Monitor™ Test Strip provides semi-quantitative indications of pH, bicarbonate, and glucose (which acts as a tracer for the acid concentrate) concentrations in final bicarbonate dialysate solutions. They can be used to monitor the proper preparation of such dialysate solutions. The Serim™ Dialysate Monitor™ Test Strips are to be used to supplement current methods for testing dialysate.

(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 A. Legrow

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K043031