K964264

510(k) SUMMARY

JUN 16 1997

High Range Peroxide Test
Reagent Strip for Testing Potency of Renalin$^{R}$ Solution

**SUBMITTER:**

Name: Wen H. Wu, Ph. D.
Address: 2931 Moose Trail
Elkhart, IN 46514
Phone: (219) 264-0025
Fax: (219) 264-2787

Contact: Wen H. Wu, Ph. D.

**Date Prepared:**
October 24, 1996

**Device Name:**

Trade Name: High Range Peroxide$^{TM}$ Strip
Common Name: Reagent Strip for Renalin$^{R}$ Peroxide
Classification Name: 876.5820 Hemodialysis System Accessories

**COMPARATIVE PRODUCT:**

Renalin Perassay$^{TM}$ 500 - Marketed by Renal System, Minneapolis, MN 55447

**DESCRIPTION OF THE NEW DEVICE:**

High Range Peroxide$^{TM}$ Strip is a paper based dry chemistry reagent strip. It consists of a single reagent pad, 0.2x0.2 inch square, adhered to one end of a 0.2x2.5 inch plastic handle with a double sided adhesive. It is a self-contained, ready to use dip-and-read reagent strip without additional reagent. The strip is packaged in 50 or 100's in bottles. Color blocks corresponding to Renalin$^{R}$ concentrations of 0.2, 0.5, 1.0, 2.0 and 3.0 % are printed on the bottle label. Quantitative estimation of Renalin$^{R}$ concentration can be made by comparing the strip color to the color blocks.

**INTENDED USE:**

High Range Peroxide$^{TM}$ Strip is intended to be used to measure Renalin concentration and to confirm the presence of 1 % or higher of Renalin$^{R}$ solution in the reprocessed kidney units. Since the strip measures actual Renalin$^{R}$ concentration from 0.2 to 3.0 % without dilution, it gives a better indication and easier management in kidney reprocessing.

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**TECHNOLOGICAL COMPARISON:**

Both the IBT High Range Peroxide™ strips and Renalin Perassay™ 500 strips are based on the oxidation of iodide to iodine by peroxide. In the case of Renalin Perassay™ 500 strip, threshold reactivity is modulated so that the strip will turn black blue only when Renalin® concentration is 1% or higher. It can only provide qualitative indication of Positive (1 % or higher) or Negative (less than 1%). In the case of High Range Peroxide™ Test, a coupler is used where the strip reactivity is modulated to provide a continuous reaction range with Renalin from 0.2 to 3.0 % or equivalent peroxide levels from 100 to 1,500 ppm. It can be used as a quantitative test for Renalin® or other peroxide disinfectants.

**SUBSTANTIAL EQUIVALENCY STATEMENT:**

Both the IBT High Range Peroxide™ Test and Renalin Perassay™ 500 Test are equally effective in detecting Positive, i.e., 1 % or higher, of Renalin® concentration in the kidney reprocessing solution. Renalin Perassay™ 500 Test, however, can only provide qualitative Positive or Negative indication of Renalin® concentration above or below 1 %. IBT High Range Peroxide™ test, on the other hand, will give quantitative results and provide more accurate indication of effective Renalin® concentration.

Submitter: Wen H. Wu Date: Oct 30. 96

Wen H. Wu, Ph. D.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 16 1997

Wen H. Wu, Ph.D.
President
Integrated Biomedical Technology, Inc.
2931 Moose Trail
Elkhart, Indiana 46514

Re: K964264
High Range Peracid Test Strips
Dated: March 15, 1997
Received: March 18, 1997
Regulatory class: II
21 CFR §876.5820/Product codes: 78 FKP and LIF

Dear Dr. Wu:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4616. 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/dsmamain.html".

Sincerely yours,

Lillian Yin, Ph.D.
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): K964264

Device Name: High Range Peroxide Reagent Strip

Indications For Use:

**Indications for Use:** K964264

High Range Peroxide™ Test Strip is intended for use as an efficacy test strip for measuring effective levels of peroxide in Renalin® disinfectant solution. Each time when the kidney unit is reprocessed with peroxide disinfectant solution such as Renalin® , the reprocessing solution should be monitored with the High Range Peroxide™ Test Strip to assure that Renalin® concentration is 3% as it is intended to be. After the kidney is placed under storage until next use, the Renalin® concentration in the disinfectant solution should be checked again before rinsing with the strip to assure that Renalin® concentration has been maintained at 1% or higher. If the Renalin® concentration drops below 1%, the kidney unit has to be either reprocessed or discarded.

Ellen Wu 10-30-96

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert D Nathing

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K964264

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

(Optional Format 1-2-96)