

K974021

510(K) SUMMARY

DEC 19 1997

510(k) Number: K974021

Product Name: Signal™ One-Step Pregnancy Test Kit

Submitted by: SA Scientific, Inc.
4919 Golden Quail
San Antonio, TX, 78240

Contact: Mike Crisp
Ph: (210) 699-8800
Fax: (210) 699-6545

Product Name: Signal™ One-Step Pregnancy Test Kit

Classification: Human chorionic gonadotropin (hCG) test system

Intended Use: Rapid one-step visual test for the qualitative detection of hCG in human urine to aid in the diagnosis of pregnancy. This test is intended for over-the-counter home use.

Description of Device: Signal™ detects the presence of hCG in urine by using a combination of polyclonal and monoclonal antibodies on the reagent pad and the test strip. The assay begins functioning with the addition of urine onto the absorbent wick. Through capillary action the urine is pulled along the membrane to the reagent pad where the hCG reacts with the conjugate. Positive results are determined by two colored lines in the window. The absence of hCG produces only one colored line in the window.

Substantial Equivalence Device: Be Sure® Plus Pregnancy Test Kit

Clinical Reference Device: SAS™ Pregnancy Strip

Performance Data: Specificity, Sensitivity & Accuracy, Interfering Substances, and Stability Studies resulted in >99% acceptance. A laboratory Comparison Study of 100 test devices with SAS™ Pregnancy Strip Test Kits resulted in >99% accuracy.

Date Originally Prepared: October 28, 1997



DEC 19 1997

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Dr. Harbi Shadfan
• President
SA Scientific, Inc.
4919 Golden Quail
San Antonio, Texas 78240

Re: K974021
Signal™ Pregnancy Test Kit
Regulatory Class: II
Product Code: LCX
Dated: October 21, 1997
Received: October 22, 1997

Dear Dr. Shadfan:

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 (Pre-market 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 pre-market 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.

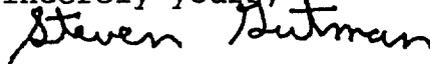
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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 (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

Indications For Use

510(k) Number: K974021

Device Name: Signal™ Pregnancy Test Kit

"Indications For Use" - Signal™ is a visual and rapid test for the qualitative determination of human chorionic gonadotropin (hCG) in urine to aid in early detection of pregnancy. This test is intended for over-the-counter use.

J. M. Chandra for AW Montgomery
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K974021

(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)

JK