K983113

NOV 18 1998

Attachment 9

Summary of Safety and Effectiveness

BeSure Plus OneStep Ovulation Prediction test is a Syntron Bioresearch, Inc. name for OTC use of solid phase immunoassay in vitro diagnostic test kit for the qualitative determination of Luteinizing Hormone (LH) in urine. BeSure Plus OneStep Ovulation Prediction test is based on comparative data with BeSure OneStep Ovulation Predictor test, a qualitative test for the determination of Luteinizing hormone currently being marketed by Syntron Bioresearch, Inc.

The BeSure Plus OneStep Ovulation Prediction Test is a sandwich solid phase dye-conjugate non-enzyme immunoassay. As the urine specimen is added to the reaction device, the gold-sol-anti-β LH antibody conjugate binds to the LH that exists in the urine specimen forming an antibody-antigen complex. This complex then migrates to the positive reaction zone and binds to the anti α LH antibody that is immobilized there by forming an antibody-antigen-antibody dye conjugate sandwich, which produces a rose-pink color band. In the absence of LH, there is no rose-pink color band that appears in the positive reaction zone. The remaining dye conjugate continues to flow up the absorbent device by passing through the positive reaction zone. This produces a rose-pink color band in the control reaction zone as immobilized antibody captures the unbound dye conjugate, demonstrating that the reagents and device are functioning correctly. This working principle can also be applied for the BeSure OneStep Ovulation Prediction test.

The exact differences in reagent between the two protocols are as follows:		
	BeSure Plus OneStep Ovulation Predictor Test	**BeSure OneStep Ovulation Predictor Test (K951538)**
Specimen Volume	Midstream	4 drops of urine
Reagent	No Reagent	No Reagent
Incubation	5 minutes	5 minutes
Steps	1 Step	1 Step
Surge Cutoff	≥ 30 mIU/ml	≥ 30 mIU/ml

Test results obtained by 100 consumers using BeSure Plus OneStep Ovulation home test showed a 99% correlation with results independently obtained by laboratory technicians using other commercially available onestep ovulation test. The results were further confirmed by having the laboratory technicians assay the patient's urine to determine the amount of LH for every testing day by using Syntron's Quantitative LH EIA test (K871602/A). The data obtained from the LH EIA test (Syntron) indicated that LH concentration equal or greater than 30 mIU/ml exhibits LH surge while LH concentration less than 30 mIU/ml exhibits no surge in BeSure Plus OneStep ovulation test, which is comparable to other commercially available onestep ovulation test kit (K951538). In this study, the laboratory technicians did not know the outcome of the consumer's test results.

These results show that nontechnical users of BeSure Plus OneStep home Ovulation Predictor Kits are able to detect the onset of the LH surge with precision comparable to that obtained by a reference immunoassay performed by trained laboratory technicians. Copies of consumer's reports are attached at the end of this report. The contact person for this Summary of Safety and Effectiveness report is provided by:

Charles Yu
Syntron Bioresearch, Inc.
2774 Loker Avenue West
Carlsbad, CA 92008
Tel: 760-930-2200
Fax: 760-930-2212

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 18 1998

Mr. Charles Yu
General Manager
Syntron Bioresearch, Inc.
2774 Loker Avenue West
Carlsbad, California 92008

Re: K983113
Trade Name: BeSure Plus OneStep Home Ovulation Predictor Test Kit
Regulatory Class: I
Product Code: CEP
Dated: August 26, 1998
Received: September 4, 1998

Dear Mr. Yu:

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) 594-4588. 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/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

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): K983113

Device Name: BeSure Plus OneStep home Ovulation Predictor Test Kit.

Indication For Use:

BeSure Plus ~~Midstream~~ OneStep Ovulation Home predicator test is a solid phase immunoassay in vitro diagnostic test kit. It is intended for over the counter use for the qualitative determination of leutinizing hormone (LH) in urine. This test kit is utilized to determine when the female body will ovulate, the most likely time for conception to occur.

(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)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K983113