K041165

JUN 17 2004

510(k) SUMMARY

Date of Summary: 23 April 2004

Product Name:
FSH Menopause Predictor Test

Sponsor's Name:
ACON Laboratories, Inc.
4108 Sorrento Valley Boulevard
San Diego, CA 92121

Sponsored by:
ACON Laboratories, Inc.
4108 Sorrento Valley Boulevard
San Diego, CA 92121
FDA Establishment Registration: 2531491

Manufactured by:
ACON Biotech (Hangzhou) Co. Ltd.
398 Tianmushan Road
Gudang Industrial Park
Hangzhou, P.R. China 310023

Correspondent in the U.S.:
Fran White
MDC Associates
163 Cabot Street
Beverly, MA 01963

Substantially Equivalent Devices:
Product: InstaCheck® FSH Menopause Test
Manufactured by: Applied Biotech, Inc.
510(k) Number: K023408

PRODUCT DESCRIPTION:

The FSH Menopause Predictor Test is a midstream test used for the qualitative measurement of FSH and the detection of Follicle Stimulating Hormone in a woman's urine as an aid in predicting menopause. The FSH predictor test is intended for use outside the body (*in vitro* diagnostic use) by women at home. FSH Menopause Predictor is an over-the-counter (OTC) device and may be sold under various private labels.

INTENDED USE:

The FSH Menopause Predictor Test is a qualitative, one-step, midstream assay for the detection of Follicle Stimulating Hormone (FSH) in urine to be used as an aid in predicting menopause. The FSH Menopause Predictor Test is intended for over-the-counter use by the lay consumer.

SUMMARY OF TECHNOLOGY:

The FSH Menopause Predictor Test employs a unique combination of mouse monoclonal-dye conjugate and goat polyclonal-solid phase antibodies to selectively identify Follicle Stimulating Hormone (FSH) in urine. As the urine flows through the absorbent portion of the device, the antibody-dye conjugate binds to the FSH forming an antibody-antigen complex. This complex binds to the anti-FSH antibody in the reaction zone and produces a pink-rose color band (T Line) that shows up within 3 minutes. When the FSH concentration is equal to or greater than 25 mIU/mL, the color intensity of the test line is equal to or greater than that of the reference line. When the FSH concentration is lower than 25 mIU/mL, the color intensity of the test line is lighter than that of the reference line. In the absence of FSH, there is no Test line formation. Test should not be read after 8 minutes have passed since sample application. The formation of a pink-rose color band (Reference Line) in the reference line area indicates that adequate sample volume has been applied and proper wicking has occurred.

PERFORMANCE DATA:

A clinical trial was done to compare the performance of the FSH Menopause Predictor Test to a substantially equivalent product (InstaCheck®) manufactured by ABI. Data clearly demonstrate that the performance of the FSH Menopause Predictor Test is substantially equivalent to the InstaCheck®.

InstaCheck® vs. FSH Menopause Predictor Test

70 females tested the FSH Menopause Predictor Test to determine their respective FSH levels during the first week of cycle (Days 2 through 7, with Day 1 as the first day of menstruation). The test was repeated one week later. If the participant was no longer having regular periods, they took the test at any time during the month and repeated with the second test one week later. Each volunteer conducted the testing at home according to the package insert instructions. The urine samples were provided to the study coordinator for testing. The study coordinator tested each sample using the FSH Menopause Predictor Test and the InstaCheck®. The data obtained was recorded as Negative or Positive.

Summary of Results

ACON FSH Menopause Predictor Test (trained Lab Tech) vs. InstaCheck®
Accuracy >99% (99% - 99%)*

ACON FSH Menopause Predictor Test (consumer) vs. ACON FSH Menopause Predictor Test (trained Lab Tech)
Accuracy = 94% (92.1% - 95.6%)*

ACON FSH Menopause Predictor Test (Consumer) vs. InstaCheck®
Accuracy = 94% (92.1% - 95.6%)*

*Denotes 95% Confidence Interval

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 17 2004

Acon Laboratories, Inc.
c/o Ms. Fran White
Regulatory Consultant
MDC Associates
163 Cabot Street
Beverly, MA 01915

Re: k041165
Trade/Device Name: FSH Menopause Predictor Test
Regulation Number: 21 CFR 862.1300
Regulation Name: Follicle- Stimulating hormone test system
Regulatory Class: Class I
Product Code: CGJ
Dated: June 8 2004
Received: June 9, 2004

Dear Ms. White:

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 (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 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/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041165

Device Name: FSH Menopause Predictor Test

Indications for Use:

FSH Menopause Predictor Test is a qualitative, one-step, midstream assay for the detection of Follicle Stimulate Hormone (FSH) in urine to be used as an aid in predicting menopause. The FSH Menopause Predictor Test is intended for over-the-counter use by the lay consumer.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use √ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Carol C. Benson
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K041165

(Posted November 13, 2003)