K070484

510(k) SUMMARY

OCT 2 2 2007

Date of Summary:
September 23, 2007

Sponsor's Name:
QuantRx Biomedical Corporation
5920 NE 112th Avenue
Portland, OR 97220
Telephone: 503-225-4557

Official Correspondent:
Dr. William H. Fleming
Phone: 503-225-4557
e-mail: whfleming@quantrx.com

Proprietary name of device:
QuantRx Female Fertility Test

Generic name of device:
Follicle Stimulating Hormone (FSH) Test, Over the Counter

Product code:
NGA [Follicle Stimulating Hormone (FSH) Test, Over the Counter]

Regulatory Classification:
21 CFR 862.1300
Class I, limitation of exemption exists [862.9 (c) (9)]

Legally Marketed Predicate Devices:

Fertell Female Fertility Test (k032002)

Surestep FSH Menopause Test (k010556)

FSH Menopause Predictor Test (k041165)

DPC IRMA serum FSH (k893976)

Product Description:

The QuantRx Female Fertility Test is a rapid, immunochromatographic assay for the measurement of follicle-stimulating hormone (FSH) in human urine. The test is performed on day 3 of the menstrual cycle by urinating directly on the absorbent tip or by dipping it in a cup of urine, and observing for the formation of colored lines after 10 minutes. A test line of color intensity greater than or equal to the reference line indicates an FSH level of at least 10 mIU/mL is indicative of diminished ovarian reserve, which corresponds to reduced fertility. A test line intensity of less than the reference line is indicative of normal ovarian reserve.

Intended Use

The QuantRx Female Fertility Test is intended to measure follicle-stimulating hormone (FSH) in urine as an ancillary screen of fertility for home use by women who are attempting to conceive.

Summary of Technology:

The QuantRx Female Fertility Test is a two-site, lateral-flow immunoassay for the measurement of follicle-stimulating hormone (FSH) in human female urine. The test employs mouse monoclonal anti-FSH antibody bound to a colloidal gold conjugate as the labeled antibody. As the urine migrates along the sample tip into the absorbent pad, FSH in the urine binds to the labeled antibody forming an antigen-antibody complex. This resulting complex continues to migrate along the test it binds to the anti-FSH capture antibody on the nitrocellulose membrane producing a colored line in the Test (T) section. The intensity of the colored line in the test section at a 10 minute read time is compared with the intensity of the Reference line which is calibrated at 10 mIU/mL of FSH. When the FSH concentration in the urine is less than 10 mIU/mL, the color intensity of the test line is lighter than the reference line. An FSH concentration of less than 10 mIU/mL on the third day of menses is usually indicative of normal ovarian reserve. When the FSH concentration in the urine is equal to or greater than 10 mIU/mL, the color intensity of the test line is equal to or darker than the reference line. An elevated FSH result (equal to or greater than 10 mIU/mL on the third day of menses) is generally indicative of a diminished ovarian reserve.

At the end of the nitrocellulose membrane is a Control section which produces a visible line if the test has been performed properly. The Control line is generated by an antigen/antibody reaction different from the FSH aspect. This Control line should always appear, regardless of the presence or absence of detectable FSH in the urine sample. The absence of a line in the Control section is considered an "invalid" result since it indicates the test did not perform properly due to procedural error or insufficient specimen.

Performance Data:

An over-the-counter study consisting of two-hundred nine (209) females was conducted comparing the performance of the QuantRx Female Fertility Test to a published, validated, quantitative, chemiluminescent method for urine follicle-stimulating hormone (FSH). In addition to the consumer study, a professional study comparing the performance of the QuantRx Female Fertility Test to this laboratory methodology was conducted using the same combination of freshly-collected urine specimens and blinded control specimens as the consumer study.

In a supplemental consumer study, a total of forty-eight (48) females performed the QuantRx Female Fertility Test using urine specimens where forty (40) of those specimens were derived from consumers who also provided paired serum specimens for comparison with an FDA cleared serum FSH assay (DPC IRMA FSH; k893976). A professional study comparing the performance of the QuantRx Female Fertility Test to the serum FSH results using the same paired urine specimens was also conducted. The concordance for both the professional and layperson users between the laboratory urine method, the FDA cleared serum method and the QuantRx Female Fertility Test demonstrated that the QuantRx Female Fertility Test is safe and effective for its stated intended use.

Summary of Findings:

Primary Study:

a. Concordance (trained user) between proposed device vs. laboratory method: 89%
b. Concordance (layperson) between proposed device vs. laboratory method: 88%
c. Concordance trained user vs. layperson for primary study: 98%

Supplemental Study:

d. Concordance (trained user) between proposed device vs. predicate: 94%
e. Concordance (layperson) between proposed device vs. predicate: 92%
f. Concordance trained user vs. layperson for supplemental study: 98%

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 22 2007

QuantRx BioMedical Corporation
c/o Ms. Lorraine C. Cogan
Emergent Technologies Consortium
14033 Stoney Gate Place
San Diego, CA 92128

Re: k070484
Trade/Device Name: QuantRx™ Female Fertility Test
Regulation Number: 21 CFR§862.1300
Regulation Name: Follicle-stimulating hormone test system.
Regulatory Class: Class I
Product Code: NGA
Dated: September 23, 2007
Received: September 26, 2007

Dear Dr. Fleming:

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 (240) 276-0490. 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 (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., 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): k070484

Device Name: QuantRx™ Female Fertility Test

Indications For Use:

The QuantRx™ Female Fertility Test is intended to measure follicle-stimulating hormone (FSH) in urine as an ancillary screen of fertility for home use by women attempting to conceive.

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

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C Benson

...ision Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

K070484