510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

k070484

B. Purpose for Submission:

New device

C. Measurand:

Follicle-stimulating hormone (FSH)

D. Type of Test:

Qualitative

E. Applicant:

QuantRx Biomedical Corporation

F. Proprietary and Established Names:

QuantRx™ Female Fertility Test

G. Regulatory Information:

1. Regulation section:

   21 CFR 862.1300, Follicle-stimulating hormone test system

2. Classification:

   Class I, meets limitations of exemptions 21 CFR 862.9(c)(9)

3. Product code:

   NGA – Test, Follicle Stimulating Hormone (FSH), Over the Counter

4. Panel:

   Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See Indication(s) for use below.

2. Indication(s) 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.

3. Special conditions for use statement(s):

   The device is intended for over-the-counter use. The test can not be used to determine ovulation. The test does not detect all kinds of fertility issues. The test may not be accurate if pregnant at the time of testing. The test can not be used for birth control.

4. Special instrument requirements:

   None required

I. Device Description:

The kit consists of a plastic-housed test device and package insert. The test device is an immunoassay containing mouse monoclonal anti-human antibody of FSH conjugated to colloidal gold and monoclonal anti-human FSH as a capture antibody on the nitrocellulose membrane. The nitrocellulose membrane also bears a reference line that corresponds to an FSH concentration of 10 mIU/mL and a control line to indicate procedural error or insufficient specimen.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Fertell Female Fertility Test

2. Predicate K number(s):

   k032002

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Indications for Use	Qualitative detection of FSH in urine as an ancillary screen of fertility	Same
Principle	Two-site lateral flow immunoassay	Same
Calibration Reference	WHO 2nd IRP 78/549	Same

Differences		
Item	Device	Predicate
Result Read Time	10 minutes	30 minutes

K. Standard/Guidance Document Referenced (if applicable):

Labeling of Home Use In-Vitro Testing Products, Clinical and Laboratory Standards Institute (CLSI [formerly NCCLS]), GP-14A, 1996

L. Test Principle:

The test is a two-site, lateral-flow immunoassay that is read visually.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

The cut-off of the test is 10 mIU/mL. Seven control solutions (pooled urine samples from males and females) were created with target FSH concentrations of 0, 2.5, 5, 7.5, 10, 12.5, and 25 mIU/mL using a WHO 78/549 determined reference solution. Each solution was then run one time on the QuantRx Female Fertility Test for ten consecutive days. The results were as follows:

Test Solution	Normal	Elevated
0.0 mIU/mL	10	0 (0%)
2.5 mIU/mL	10	0 (0%)
5.0 mIU/mL	8	1 (11%)
7.5 mIU/mL	7	3 (30%)
10.0 mIU/mL	3	7 (70%)
12.5 mIU/mL	0	10 (100%)
25.0 mIU/mL	0	10 (100%)

The sponsor provided data from a study of urine and serum samples taken from 40 female subjects to demonstrate performance around the cut-off. The results from professionals testing the device were as follows:

	Serum FSH			
QuantRx™	Weak Normal	-25% of Cutoff	+25% of Cutoff	Strong Elevated
Elevated	2	0	2	8
Normal	23	4	0	1

b. *Linearity/assay reportable range:*

Not applicable

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

The test is calibrated against the WHO 2nd IRP 78/549 of FSH.

d. *Detection limit:*

Seven control solutions (pooled urine from males and females) were created with target FSH concentrations of 0, 2.5, 5, 7.5, 10, 12.5, and 25 mIU/mL using a WHO 78/549 determined reference solution. The QuantRx Female Fertility Test was assayed one time on ten consecutive days using each solution. The strips were removed and digitally photographed, then quantitated using Adobe Photoshop. A dose response curve was calculated from the means of each concentration. The lower limit of detection (LLD) was calculated from the SD around the 2.5 mIU/mL calibrator. The 95% confidence interval (2SD from the zero value) was used to determine the LLD from the standard fit to the curve. That value was calculated to be 0.6 mIU/mL.

e. *Analytical specificity:*

To determine potential cross-reactivity, the QuantRx Female Fertility Test was analyzed using solutions with FSH 50% above or 50% below the assay threshold of 10 mIU/mL and spiked with high physiological concentrations of luteinizing hormone (LH), human chorionic gonadotropin (hCG), and thyroid stimulating hormone (TSH). The results showed no cross-reactivity from TSH at 20 µIU/mL or LH at 100 mIU/mL. High levels of hCG (up to 100,000 mIU/mL) were not cross reactive (e.g., did not produce a test line signal). However, negative interference of a positive FSH signal was observed at high hCG levels. This was addressed with a limitation in the labeling about inaccurate results being obtained during pregnancy.

In addition to the hormones listed above, the QuantRx Female Fertility Test was tested for interference using solutions with FSH 50% above or 50% below the assay threshold of 10 mIU/mL and spiked with the following compounds at a level 100 µg/mL: ascorbic acid, acetaminophen, albumin, bilirubin, caffeine, glucose, hemoglobin, and serum protein. No interference was observed.

f. Assay cut-off:

See Precision/Reproducibility.

2. Comparison studies:

a. Method comparison with predicate device:

A comparison study was conducted to demonstrate concordance between results from the proposed device and an legally marketed serum FSH device. A total of 40 peri-menopausal age women (35 to 50 years old) were recruited. Each of the test subjects collected their own urine and conducted testing on the proposed device, using the dip method as described in the labeling. The urine specimens were subsequently tested by professionals. Upon completion of the urine testing, each subject provided a matching blood sample which was analyzed on the serum FSH device. The results of the consumer and professional analyses of the proposed device and corresponding serum results, which ranged from 1.9 to 96.1 mIU/mL, are shown in the following tables:

Professional	**Elevated ≥10 mIU/mL**	**Positive Agreement**	**Normal <10 mIU/mL**	**Negative Agreement**
QuantRx™	10	91%	27	93%
Serum FSH	11		29	

Consumer	**Elevated ≥10 mIU/mL**	**Positive Agreement**	**Normal <10 mIU/mL**	**Negative Agreement**
QuantRx™	9	81%	27	93%
Serum FSH	11		29	

Supplemental testing was performed using eight spiked solutions around the cutoff. The solutions were created from a WHO FSH standard, targeted to 8.0 mIU/mL and 12.0 mIU/mL, and blind labeled. The solutions were then analyzed on the proposed device by eight consumers and subsequently tested by a professional. All twelve specimens (four clinical and eight contrived) that fell within the ± 20% of the cutoff were correctly interpreted by the consumers and professional. The results of the consumer and professional analyses of the proposed device and corresponding serum results or spiked

urine, with the original and supplemental data, are shown in the tables below:

Professional	**Elevated ≥10 mIU/mL**	**Positive Agreement**	**Normal <10 mIU/mL**	**Negative Agreement**
QuantRx™	16	94%	29	94%
Serum FSH Spiked Urine	17		31	

Consumer	**Elevated ≥10 mIU/mL**	**Positive Agreement**	**Normal <10 mIU/mL**	**Negative Agreement**
QuantRx™	15	88%	29	94%
Serum FSH Spiked Urine	17		31	

The overall professional agreement was 94%. The overall consumer agreement was 92%. The concordance of the professional vs. consumer was 98%.

Another comparison study was conducted to demonstrate concordance between the results from the proposed device performed by professionals and a quantitative FSH laboratory device. A total of 69 fresh urine specimens and 140 blinded, coded specimens were used in the study. The fresh urine specimens represented various stages of each subject's cycle including day 3 of menses and were found to range from <0.3 to 122.8 mIU/mL. The coded specimens were banked urine specimens of known FSH concentration ranging from 1.4 to 17.3 mIU/mL. The results were as follows:

	Elevated ≥10 mIU/mL	**Positive Agreement**	**Normal <10 mIU/mL**	**Negative Agreement**
Professional	55	71%	131	99%
Comparator FSH Lab Method	77		132	

The overall agreement between the new device (when performed by professionals) and the comparative device is 89%.

b. Matrix comparison:

Not applicable

3. Clinical studies:

a. *Clinical Sensitivity:*

Not applicable

b. *Clinical specificity**:***

Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):

A study was conducted to demonstrate the ability of lay persons to correctly interpret the test results compared with the results from a quantitative, laboratory FSH method. A total of 209 female subjects representing various demographics participated. Sixty-nine (69) of the subjects conducted testing using their own specimens via the midstream procedure and provided a urine sample for quantitation. The remaining 140 subjects were provided blinded urine specimens of previously determined FSH concentrations and conducted the testing using the dip procedure.

Fifteen (15) of the proposed devices used in this study were modified to mimic invalid test results. This was accomplished by removing the conjugate pad located between the sample wick and the nitrocellulose membrane. All 15 subjects given the modified devices correctly interpreted the results as invalid and were given another device to repeat testing. The replacement devices were unmodified and produced valid results. The results from the consumer study, including those from the consumer questionnaire, are below.

	Elevated ≥10 mIU/mL	**Positive Agreement**	**Normal <10 mIU/mL**	**Negative Agreement**
Consumers	54	70%	130	98%
Comparator FSH Lab Method	77		132	

The overall agreement between the new device (when tested by consumers) and the comparative lab FSH device is 88%.

The consumer questionnaire results showed that out of 191 consumers, 100% thought the written instructions were clear and easy to follow. Also, 100% felt the new test was easy to perform.

The results of a comparison of the consumer performing the test versus the professional performing the test are shown below:

	Elevated ≥10 mIU/mL	Positive Agreement	Normal <10 mIU/mL	Negative Agreement
Consumer	54	98%	130	99%
Professional	55		131	

The results demonstrate that the performance of the QuantRx Female Fertility Test in the hands of the lay user is comparable to the performance in the hands of a trained professional.

4. Clinical cut-off**:**

   Not applicable

5. Expected values/Reference range:

   The expected values are based on literature.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.