

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE**

A. 510(k) Number: K032992

B. Analyte: human chorionic gonadotropin

C. Type of Test: qualitative solid phase chromatographic immunoassay

D. Applicant: Biotech Atlantic Inc.

E. Proprietary and Established Names: UniMark® Home Pregnancy Test Device

F. Regulatory Information:

1. Regulation section:
21CFR862.1155, Human Chorionic Gonadotropin Test System
2. Classification: Class II
3. Product Code: LCX
4. Panel: Chemistry (75)

G. Intended Use:

1. Indication(s) for use: The UniMark® Home Pregnancy Test Device (provided as a test strip contained within a plastic test strip holding cassette) is for the rapid and qualitative determination of human Chorionic Gonadotropin (hCG) in urine. It is intended for consumer use at home. It is indicated for use in the early detection of pregnancy.
2. Special condition for use statement(s):
3. Special instrument Requirements:

H. Device Description:

The device includes a test strip within a cassette holder and a dropper for application.

I. Substantial Equivalence Information:

1. Predicate device name(s): UniMark® hCG Pregnancy Test device
2. Predicate K number(s): K941090
3. Comparison with predicate: The device is the same device as the predicate. The difference is that the indications for use is expanded to include over-the-counter use. It is indicated for use in the early detection of pregnancy

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

None referenced

K. Test Principle: The test is a solid phase chromatographic immunoassay.

L. Performance Characteristics (if/when applicable):1. Analytical performance:

All analytical and method comparison studies were performed previously on the predicate device. Therefore, only the over-the counter lay user study was included in this 510(k).

a. *Precision/Reproducibility:* Qualitative assay:

Reproducibility of the device in the hands of lay users was evaluated in a consumer study of 100 users selected on a random basis as they presented themselves at study sites. Participants ranged in age from 16 to over 40 and ranged in education level from high school to graduate levels. Participants were given a set of coded samples containing spiked specimens at concentrations of 0, 20, 30 and 1000 mIU/ml. The only instructions provided were draft copies of the home use package insert. All samples at 30 mIU and 1000 mIU/ml tested positive. Results were compared to those obtained by laboratory professionals. In this study there was 100% agreement between results obtained by lay users and those obtained by professionals.

b. *Linearity/assay reportable range:* Not applicable - qualitative testc. *Traceability (controls, calibrators, or method):* Reviewed in the 510(k) for the predicate device. WHO 3rd IS 75/357d. *Detection limit:* Reviewed in the 510(k) for the predicate device.e. *Analytical specificity:* Reviewed in the 510(k) for the predicate device.f. *Assay cut-off:* 25 mIU/ml. Reviewed in the 510(k) for the predicate device.2. Comparison studies:a. *Method comparison with predicate device:*

Comparison to professional use device is described in the reproducibility section above.

3. Clinical studies:a. *Clinical sensitivity:* Not applicable. Not typically provided for this device type.

b. Clinical specificity: Not applicable. Not typically provided for this device type.

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

4. Clinical cut-off: Not applicable. Not typically provided for this device type.
5. Expected values/Reference range: Not applicable. Qualitative assay.

M. Conclusion:

I recommend that the Biotech Atlantic Inc. UniMark® Home Pregnancy Test Device is substantially equivalent to the predicate device.