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

A. 510(k) Number:

k122907

B. Purpose for Submission:

Addition of over-the counter claim

C. Measurand:

Human Chorionic Gonadotropin (hCG)

D. Type of Test:

Qualitative chromatographic immunoassay

E. Applicant:

Polymed Therapeutics, Inc.

F. Proprietary and Established Names:

Fastep™ At-Home Pregnancy Test

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
LCX	Class II	21 CFR 862.1155, Human Chorionic Gonadotropin (hCG) test system	75 Clinical Chemistry (CH)

H. Intended Use:

1. Intended use(s):

   See Indications for Use below

2. Indication(s) for use:
   The Polymed Therapeutics' Fastep™ At-home Pregnancy Test is a rapid chromatographic immunoassay for the visual, qualitative detection of human chorionic gonadotropin (hCG) in urine specimen to aid in the early detection of pregnancy.

   Polymed Therapeutics' FastepTM At-Home Pregnancy Test is intended to be distributed

for Over-the-Counter (OTC) use.

3. Special conditions for use statement(s):

Intended for OTC use.

4. Special instrument requirements:

None, this device is a visually-read, single-use device.

I. Device Description:

The Fastep™ At-Home Pregnancy Test is designed to be tested in midstream and dipstick mode. The Fastep™ At-Home Pregnancy Test consists of a single test strip encased in plastic device housing, with an absorbent tip. The result is generated by immersing the tip in the urine stream or urine cup for a sufficient amount of time to absorb an adequate sample volume. Each test reagent strip consists of a mouse monoclonal anti-α-hCG antibody coated membrane and a dried chemical pad containing mouse monoclonal anti-β-hCG anybody colloidal gold conjugate. The control antibodies are goat anti-mouse IgG.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Teco Diagnostics One-Step Midstream Pregnancy Test

2. Predicate 510(k) number(s):

k974059

3. Comparison with predicate:

Similarities		
	Candidate Device	Predicate Device
Intended Use	Rapid qualitative detection of hCG to aid in the early detection of pregnancy.	Same
Target User	Over-the-Counter Use	Same
Specimen	Urine	Same
Test Principle	Lateral flow Sandwich Immunochromatographic Assay	Same
Positive result	2 colored lines	Same
Negative result	1 colored line	Same
Detection reagent	Colloidal gold	Same
Storage	35 – 86ºF (2 – 30ºC)	Same

Differences		
Item	Candidate Device	Predicate Device
Cutoff	20 mIU/ml	25 mIU/ml
Device Format	Midstream and Dipstick mode	Midstream mode
Read time	3 to 5 minutes	5 minutes (Do not read result after more than 30 minutes)
Traceability	WHO 4th International Standard	WHO 3rd International Standard

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

Not applicable

L. Test Principle:

The Polymed Therapeutics Fastep™ At-Home Pregnancy Tests is a qualitative, lateral flow sandwich immunochromatographic assay for the detection of human chorionic gonadotropin (hCG) in urine.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

See 510(k) decision summary for k112101

b. Linearity/assay reportable range:

See 510(k) decision summary for k112101

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

See 510(k) decision summary for k112101

d. Detection limit:

See 510(k) decision summary for k112101

e. Analytical specificity:

See 510(k) decision summary for k112101

f. Assay cut-off:

See 510(k) decision summary for k112101

2. Comparison studies:

a. Method comparison with predicate device:

The sponsor has submitted two studies to demonstrate performance in the hands of lay users:

In the first lay user study, 129 lay users self-tested using both midstream and dipstick mode, and 19 lay users tested urine samples in dipstick mode only. All lay users were instructed to read the proposed package insert (in English) to operate the device. Each lay user was also given a questionnaire to rate how well they understood the instructions. More than 97% of lay users agreed that the user instruction was written in a manner that was easy to use and understand.

Lay users' results with the new test were compared to professionals' results using the OTC predicate test (Teco Diagnostics One-Step Midstream Pregnancy Test k974059) and the results are summarized below:

1) Dipstick Mode comparison

Fastep™ At-Home Test(Dipstick)	Teco Diagnostics			
		+	-	Total
	+	58	0	58
	-	4*	85	89
	Total	62	85	147**

* Paired serum samples were also collected from each lay-user for quantitative hCG measurement (Abbott Architect i2000). The observed values from the serum results for these 4 samples were negative. .
**One "invalid" result was obtained using predicate device; therefore, only 147 dipstick mode results were tabulated.

2) Midstream Mode comparison

Fastep™ At-Home Test(Midstream)	Teco Diagnostics			
		+	-	Total
	+	51	0	51
	-	4*	72	76
	Total	55	72	127**

* Paired serum samples were also collected from each lay-user for quantitative hCG measurement (Abbott Architect i2000). The observed values from the serum results for these 4 samples were negative.
**One "invalid" result was obtained for midstream mode using predicate device and candidate device, respectively; therefore only 127 midstream mode results were tabulated.

In the second lay user study, 21 lay users were recruited to test masked, randomized urine samples in dipstick mode with hCG concentrations close to the cutoff level at 16.7, 25.3

and 38.7 mIU/mL. Each lay user tested 3 blinded samples using package insert instructions only. The lay user study results are summarized below:

hCG concentration	Lay user results
16.7 mIU/mL	21/21 negative
25.3 mIU/mL	21/21 positive
38.7 mIU/mL	21/21 positive

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):

Not Applicable

4. Clinical cut-off:

Not Applicable

5. Expected values/Reference range:

N. Proposed Labeling:

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

O. Conclusion:

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