

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

A. 510(k) Number:

K052708

B. Purpose for Submission:

For the qualitative detection of the urease enzyme in gastric mucosal biopsy specimens to aid in the presumptive determination of H. pylori in symptomatic adult patients

C. Measurand:

Urease enzyme

D. Type of Test:

Qualitative, Enzymatic

E. Applicant:

ARJ Medical Inc

F. Proprietary and Established Names:

Pylo - Plus

G. Regulatory Information:

1. Regulation section:

21 CFR Part 866.3110 Campylobacter fetus Serological Reagents

2. Classification:

I

3. Product code:

LYR – Campylobacter pylori

4. Panel:

H. Intended Use:

1. Intended use:

Pylo-Plus is intended for the qualitative detection of the urease enzyme in gastric mucosal biopsy specimens and for the presumptive determination of *Helicobacter pylori* in symptomatic adult patients.

2. Indication(s) for use:

Pylo-Plus is intended for the qualitative detection of the urease enzyme in gastric mucosal biopsy specimens and for the presumptive determination of *Helicobacter pylori* in symptomatic adult patients.

3. Special conditions for use statement(s):

For prescription use only

4. Special instrument requirements:

N/A

I. Device Description:

Pylo-Plus is packaged in boxes of 50 test slides. It consists of a dry filter paper containing urea, phenol red (a pH indicator), buffers and a bacteriostatic agent, in a sealed plastic slide. If the urease enzyme of *H. pylori* is present in an inserted tissue sample, the resulting decomposition of urea causes the pH to rise resulting in a color change from yellow to bright magenta.

J. Substantial Equivalence Information:

1. Predicate device name:

Medical Instruments Corp. Pronto Dry

2. Predicate 510(k) number:

K991248

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	Detects urease enzyme	Same
Specimen type	Gastric mucosal biopsy	Same
Target population	Symptomatic patients with gastrointestinal disorders	Same
Test principle	Color change in response to urea level from yellow to red	Same
Storage	Room temperature	Same

Differences		
Item	Device	Predicate
Clinical sensitivity	100% CI (97.0 – 100%)	78.5% CI(59.0 – 83.9%)
Clinical specificity	100% CI (97.0 – 100%)	97.8% CI (88.2 – 99.9%)

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

N/A

L. Test Principle:

A gastric mucosal endoscopic biopsy is placed in the test well of the Pylo-Plus slide. The slide is then closed and the specially designed cover is squeezed to allow transfer of the biopsy contents onto the urea containing surface. If *H. pylori* is present, the urease in *H. pylori* converts the urea to ammonia which raises the pH and changes the color of the test surface from yellow to red, indicating a positive test.

H. pylori produces large amounts of urease enzyme. Tests for gastric urease are helpful for presumptive determination of *H. pylori* because mammalian cells do not produce urease and very few micro organisms survive in the stomach, except for *H. pylori*.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

A reproducibility study was performed to determine the consistency of Pylo-Plus results between different subjects in different locations at different times

using varying levels of urease. Testing was done at 3 separate sites using 3 users at each facility. Two concentrations were at the lower limits of the testing threshold, two concentrations were at the high limits and one concentration was negative. All samples were masked. Positive and negative results were accurately recorded at each concentration so the samples produced the expected results 100% of the time.

b. Linearity/assay reportable range:

N/A

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

N/A

d. Detection limit:

N/A

e. Analytical specificity:

Bacterial cell suspensions at concentrations ranging from 10^4 to 10^8 were tested with the Pylo-Plus. At 10^7 , *Yersinia enterocolitica* was slightly positive, while at 10^8 , *Proteus mirabilis* and *Pseudomonas aeruginosa* were also positive. These microorganisms gave negative results at concentrations ranging from $10^4 - 10^6$.

f. Assay cut-off:

N/A

2. Comparison studies:

a. Method comparison with predicate device:

100 patient biopsy samples were tested with the Pylo-Plus and Pronto Dry. There were 20 positive and 80 negative results with 100% positive and negative agreement.

b. Matrix comparison:

N/A

3. Clinical studies:

a. Clinical Sensitivity:

Biopsy samples from 100 patients were tested with the Pylo-Plus. Results

were compared to patient diagnosis. 20 patients were diagnosed with H.pylori infection and 80 were negative. The Pylo-Plus results were compared to clinical diagnosis and showed a sensitivity and specificity of 100%. C.I.(97.5 – 100%)

b. Clinical specificity:

Refer to (a.) above

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

N/A

4. Clinical cut-off:

N/A

5. Expected values/Reference range:

In most cases, positive results can be expected to appear within 5 minutes. All positive results can be expected at one hour.

N. Proposed Labeling:

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

O. Conclusion:

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