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

A. 510(k) Number:
K031942

B. Analyte:
Giardia antigens

C. Type of Test:
Chromatographic immunoassay

D. Applicant:
Remel Inc.

E. Proprietary and Established Names:
Xpect™ Giardia Lateral Flow Assay

F. Regulatory Information:

1. Regulation section:
   21 CFR Part 866.3220 Entamoeba histolytica serological reagents
2. Classification:
   Class II
3. Product Code:
   MHI – Giardia spp.
4. Panel:
   83 (Microbiology)

G. Intended Use:

1. Intended use(s):
   Xpect Giardia kit is an *in vitro* qualitative immunoassay for the detection of Giardia antigens in preserved and unpreserved fecal specimens. This test is intended as an aid in the laboratory diagnosis of suspected Giardia infections.
2. Indication(s) for use:
   Xpect Giardia kit is an *in vitro* qualitative immunoassay for the detection of Giardia antigens in preserved and unpreserved fecal specimens. This test is intended as an aid in the laboratory diagnosis of suspected Giardia infections
3. Special condition for use statement(s):
   Not applicable
4. Special instrument Requirements:
   Not applicable

H. Device Description:
The kit contains 20 test devices consisting of a membrane striped with rabbit anti-Giardia, and goat anti-mouse IgG; conjugate consisting of dark-blue microparticles coated with anti-Giardia MAb, and dark blue microparticles coated with mouse IgG; specimen dilution buffer; a procedure card; disposable transfer pipettes, dilution tubes and instructions for use.

I. Substantial Equivalence Information:

1. Predicate device name(s):

BD ColorPAC Giardia/Crypto Rapid Assay

2. Predicate K number(s):
   K 983399
3. Comparison with predicate:

Similarities		
Item	**Device**	**Predicate**
Intended Use	Detection of Giardia antigens in fecal specimens	Detection of Giardia and Cryptosporidium antigens in fecal specimens
Technology	Qualitative immunochromatographic assay	Qualitative immunochromatographic assay
Antibodies:conjugate	Monoclonal anti-Giardia and normal mouse IgG	Rabbit anti-Giardia, monoclonal anti-Giardia and Cryptosporidium
Specimen type	Human stool preserved in 10% formalin, SAF or Cary Blair	Human stool preserved in 10% formalin, SAF, MIF, or Cary Blair
Differences		
Item	**Device**	**Predicate**
Capture antibodies or molecules	Rabbit anti-Giardia and goat anti-mouse IgG	Mouse anti-Cryptosporidium, goat anti-mouse IgG, avidin derivative
Material: membrane	Mylar-backed nitrocellulose	Nitrocellulose
Material: conjugate	Anti-Giardia and mouse IgG colored polystyrene particles diluted in buffer	Colloidal dye labeled monoclonal antibodies to Giardia and Cryptosporidium
Sample volume	100µl	50µl

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

Not applicable

K. Test Principle:

The Xpect™ Giardia Lateral Flow Assay is a chromatographic immunoassay that detects the presence of *Giardia* antigens. The test utilizes sample wicking to capture *Giardia* antigens on discrete test lines containing antigen-specific antibodies for each organism. A specimen is added to a dilution tube containing a buffered solution. A conjugate containing colored micro-particles linked to murine monoclonal antibody specific for *Giardia* is added. The mixture is dispensed into the sample well of the device and wicks across a membrane containing capture antibody strips. The *Giardia* immune complex if present, reacts with anti-*Giardia* antibody at the test line. Conjugates not bound at the test

lines are later captured at the control line containing anti-mouse antibody. A blue line will appear at the *Giardia* test position if *Giardia* antigen is present. A line in the Control position indicates that the test is working properly.

L. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:
Reproducibility testing was conducted at seven sites, including one in-house site, on three separate days with ten blinded samples of varying activity. All samples tested for Giardia produced the expected result.

b. Linearity/assay reportable range:
Not applicable

c. Traceability (controls, calibrators, or method):
Not applicable

d. Detection limit:
For Giardia, detection limit was 1 organism per 0.1 ml. of specimen

e. Analytical specificity:

Cross-reactivity:
No cross-reactivity was observed using samples containing the following organisms: *Ascaris lumbricoides, Blastocystis hominis, Campylobacter coli, Campylobacter jejuni, Candida albicans, Chilomastix mesnili, Cryptosporidium parvum, Cyclospora cayetanensis, Dientamoeba fragilis, Endolimax nana, Entamoeba coli, Entamoeba hartmanni, Entamoeba histolytica, Enterobius vermicularis, Escherichia coli,* hookworm, *Hymenolepis nana, Iodamoeba bütschlii, Isospora* sp., *Microsporidia,* Rotavirus, *Salmonella choleraesuis* subsp. *choleraesuis serotype Typhimurium, Shigella dysenteriae, Shigella flexneri, Shigella sonnei, Strongyloides stercoralis, Taenia* sp., and *Trichuris trichiura.* Cross-reactivity to Astrovirus and Caliciviruses has not been established.

Interfering Substances:
Prior to testing, positive and negative samples were spiked (20% v/v) with blood, mucin, fecal fat or the following over-the-counter anti-diarrheal products: Pepto-Bismol®, Imodium® A-D, and Kaopectate® (active ingredients: bismuth subsalicylate, loperamide HCl, and attapugite respectively). Testing indicated that none of these substances interfered with the expected result.

f. Assay cut-off:
The assay can detect 1 Giardia organism per 0.1ml of specimen. Clinically relevant detection limits were determined using true clinical specimens diluted to an end point titration with the Xpect Giardia test. Sequential serial dilutions were tested until an endpoint dilution was reached. The endpoint dilution was defined as one dilution above where the sample became negative. The quantity of organisms detected at the titration endpoint in each specimen was calculated from the numbers seen microscopically in a 10 µl sample using DFA.

2. Comparison studies:

a. Method comparison with predicate device:

Percent Agreement:

The Xpect™ Giardia was compared to a commercially available lateral flow test - the predicate device. The Percent Agreement of the Xpect™ Giardia assay versus the predicate device was as follows:

Giardia		**Predicate Device**		
		+	–	
Xpect™	+	24	7	
	–	2	114	**Agreement**
	Total	26	121	**93.9%** (138/147)

b. Matrix comparison:

Not applicable

3. Clinical studies:

a. Clinical sensitivity:

Sensitivity/Specificity:

The performance of the Xpect™ Giardia was evaluated at six geographically diverse laboratories. The overall sensitivity and specificity of the test were compared to microscopy. Performance relative to patients' clinical status has not been established. The overall sensitivity and specificity for *Giardia* are listed below.

Giardia		**Microscopy**	
		+	-
Xpect™	+	95	14
	-	2	464
	Total	97	478

Sensitivity: 97.9% (95/97); 95% CI = 92.8-99.4%

Specificity: 97.1% (464/478); 95% CI = 95.1-98.2%

Note : CI = Confidence Interval

b. Clinical specificity:

Refer to (a) above

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

Not applicable

4. Clinical cut-off:
   See assay cut off above
5. Expected values/Reference range:
   Expected values were established from literature. Worldwide, Giardia is the most commonly identified parasite in stool specimens with a prevalence rate of 2-5%. Incidence of giardiasis is higher in children than in adults. In the USA, the asymptomatic carriage rate of Giardia is estimated to be 3-7%. Rates tend to be higher in southern USA regions and in children younger than 36 months who attend daycare centers.

M. Conclusion:

In clinical settings, the Xpect™ Giardia Lateral Flow Assay is substantially equivalent in performance to the predicate device and to microscopic examination for the identification of Giardia in fecal specimens.