K031942

NOV 18 2003

510(k) Summary

The 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

Submitter's Identification:

Submitter's Name and Address:

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Date Summary Prepared: November 7, 2003

Device Trade Name:
Xpect™ Giardia Lateral Flow Assay

Predicate Device:
Becton Dickinson ColorPAC™ Giardia/Cryptosporidium Rapid Assay, (k)983399.

Classification Name:
Entamoeba histolytica serological reagents.
Giardia SPP 866.3220 Code: MHI

Intended Use:
REMEL'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.

Device Description:
The Xpect™ Giardia Lateral Flow Assay is a chromatographic immunoassay that detects the presence of *Giardia* antigen. The test utilizes sample wicking to capture *Giardia* antigen on a discrete test line containing antigen-specific antibodies for *Giardia*. 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 along a membrane containing capture antibody stripes. The *Giardia* immune complex, if present, reacts with anti- *Giardia* antibody at the test line. Antibody-labeled microparticles not bound at the test line are later captured at the control line containing anti-mouse antibody. A blue line of any intensity (light blue to black) will appear at the *Giardia* test position if *Giardia* antigen is present. A complete line at the Control position indicates that the test is working properly.

Comparison with Predicate Device:
The following information supports the Statement of Equivalence between the Becton Dickinson ColorPAC™ Giardia/Cryptosporidium Rapid Assay and the Xpect™ Giardia Lateral Flow Assay. The differences in technology do not raise additional concerns regarding safety and effectiveness. Safety and effectiveness are demonstrated to be substantially equivalent.

Product Feature	Becton Dickinson ColorPAC™ Giardia/Cryptosporidium Rapid Assay	Xpect™ Giardia Lateral Flow Assay
Intended Use	Detection of *Giardia* and *Cryptosporidium* antigens in aqueous extracts of fecal specimens	Detection of *Giardia* specific antigens in fecal specimens
Technology	Qualitative immunochromatographic assay	Qualitative immunochromatographic assay
Capture Antibodies or Molecules: Device	Mouse anti-*Cryptosporidium*, goat anti-mouse IgG, Avidin derivative	Rabbit anti-*Giardia*, goat anti-mouse IgG
Antibodies: Conjugate	Rabbit anti-*Giardia*, monoclonal anti-*Giardia* and *Cryptosporidium*	Monoclonal anti-*Giardia* Normal mouse IgG
Material: Membrane	Nitrocellulose	Mylar-backed nitrocellulose
Material: Conjugate	Colloidal dye labeled monoclonal antibodies to *Giardia* and *Cryptosporidium*	Anti-*Giardia* and Mouse IgG colored polystyrene particles diluted in buffer
Specimen Type	Human stool preserved in 10% formalin, SAF, MIF or Cary Blair	Human stool preserved in 10% formalin, SAF or Cary Blair
Sample volume	50µl	100µl

Specimen Stability:

- Fresh, untreated stool specimens should be stored at 2-8°C and tested within 48 hours of collection. If fresh specimens cannot be tested within 48 hours, they should be frozen at -20°C or below in a non-defrosting freezer and tested within 2 months of collection. Avoid multiple freeze-thaw cycles.
- Stool specimens treated with 10% formalin or SAF fixatives may be refrigerated at 2-8°C or stored at room temperature (20-25°C) and should be tested within 2 months of collection.
- Stool specimens collected in modified Cary Blair Transport Medium with indicator (or equivalent) should be refrigerated and tested within 1 week of collection or frozen (as above) and tested within 2 months of collection. Avoid multiple freeze-thaw cycles.
- Stool specimens that have been concentrated or treated with PVA fixatives are not suitable for use with this test.

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

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)

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.

Reproducibility:
Reproducibility testing was conducted at seven sites, including one in-house site, on three separate days with ten blinded samples of varying activity. 100% of the 630 samples tested for *Giardia* produced the expected result.

Conclusion:
Overall, the results from the clinical and POL investigation demonstrate that the Xpect™ Giardia Lateral Flow Assay is substantially equivalent to microscopic examination and the Becton Dickinson ColorPAC™ Giardia/Cryptosporidium Rapid Assay when used in accordance with the proposed labeling.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 18 2003

Richard L. Tyson, Ph.D.
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Remel Inc.
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Re: k031942
Trade/Device Name: Xpect™ Giardia
Regulation Number: 21 CFR 866.3220
Regulation Name: Entamoeba Histolytica Serological Reagents
Regulatory Class: Class II
Product Code: MHI
Dated: October 15, 2003
Received: October 17, 2003

Dear Dr. Tyson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K031942

Device Name: Xpect™ Giardia

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(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence Of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K031942