K982764

DEC - 3 1998

A. 510(k) Summary

Identification Information

Submitter's Information:

Submitter's Name and Address:

Meridian Diagnostics, Inc.
River Hills Drive
Cincinnati, OH 45244

Phone Number: 1-800-543-1980

Contact Person: Allen D. Nickol, PhD
Director of Clinical and Regulatory Affairs

Date Summary Prepared: August 5, 1998

Name of Device: Premier *Cryptosporidium*.

Classification Name:
Cryptosporidium spp. (MHJ)

Predicate Equivalent Device:
ProSpecT *Cryptosporidium* Microplate Assay

Description of Device:
The assay is a conventional microwell sandwich enzyme immunoassay, utilizing polyclonal capture and monoclonal detection antibodies.

Intended Use:
The Premier *Cryptosporidium* enzyme immunoassay (EIA) is an in *vitro* qualitative procedure for the detection of *Cryptosporidium* antigens in stool. Test results are intended to aid in the diagnosis of *Cryptosporidium* infection.

Comparison with Predicate Device:
The following comparison of the use, technology, function and performance supports the Statement of Equivalence between the **Premier *Cryptosporidium*** test and the ProSpect Cryptosporidium Microplate Assay. The differences do not

raise additional concerns regarding safety and effectiveness. Safety and effectiveness are demonstrated to be substantially equivalent.

Method	Premier *Cryptosporidium*	Alexon ProspecT *Cryptosporidium*
Intended Use	Detection of *Cryptosporidium antigens* in patient stool	Detection of *Cryptosporidium* Antigen in aqueous extracts of fecal specimens
Results	Qualitative	Qualitative
Specimen Required	Preserved (Formalin, SAF) and Unpreserved Stools	Preserved (Formalin, SAF, MF), Unpreserved Stool, and stools in C&S (or equivalent) transport media
Technology	Sandwich Enzyme Immunoassay Polyclonal capture, monoclonal detect, polyclonal conjugate, TMB substrate	Sandwich Enzyme Immunoassay Polyclonal capture, monoclonal conjugate, TMB substrate
Level of Skill Required	Laboratory Technician	Laboratory Technician
Function	Specimen diluted 1/4 and 200µl added to well containing rabbit *anti-Cryptosporidium* capture Ab. Incubate 1 hr at room temperature. Wash 5 times. Add 2 drops detection Ab and two drops enzyme conjugate per well. Incubate 30 minutes at room temperature. Wash 5 times. Add 4 drops substrate. Incubate 10 minutes at room temperature. Add two drops stop solution and read visually or spectrophotometrically	10. Sample preparation varies with specimen type. Some are diluted ¼, others are not diluted. Add 0.2ml to wells. 11. Incubate 1 hr at room temperature. 12. Wash 3 times. 13. Add 4 drops Enzyme Conjugate. 14. Incubate 30 minutes at room temperature 15. Wash 5 times. 16. Add 4 drops Substrate 17. Incubate 10 minutes at room temperature. 18. Add 1 drop Stop Solution and read visually or spectrophotometrically
Interpretation	Pos/Neg read visually or spectrophotometrically. Fixed cutoff 0.140 single wavelength (450nm) or 0.100 dual wavelength (450-630nm)	Pos/Neg read visually or spectrophotometrically. Color chart for visual; single wavelength read pos if ≥0.05 absorbance units above negative control
Performance vs. Reference Methods		
Sensitivity	100%	97%
Specificity	99%	98%

Interfering Substances: None observed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC - 3 1998

Allen D. Nickol, Ph.D.
Director of Clinical and
Regulatory Affairs
Meridian Diagnostics, Inc.
3471 River Hills Drive
Cincinnati, Ohio 45244

Re: K982764
Trade Name: Premier *Cryptosporidium*
Regulatory Class: II
Product Code: MHJ
Dated: October 21, 1998
Received: October 22, 1998

Dear Dr. Nickol:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

This letter will allow you to begin marketing your device as described in your 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 advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html"

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

E. Indications for Use Statement

510(k) Number (if known): K 982764

Device Name: Premier *Cryptosporidium*

Indications For Use:

The Premier *Cryptosporidium* enzyme immunoassay (EIA) is an *in vitro* qualitative procedure for the detection of *Cryptosporidium* antigens in stool. Test results are intended to aid in the diagnosis of *Cryptosporidium* infection.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Woody Dubois

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K982764

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use
(Optional Format 1-2-96)