AUG -9 1999

510(k) Summary

Identification Information

Submitter's Information:

Submitter's Name and Address:

Meridian Diagnostics, Inc.
3471 River Hills Drive
Cincinnati, OH 45244

Phone Number: 1-800-696-0739
FAX Number: 1-513-272-5432

Contact Person: Allen D. Nickol, PhD
Director of Clinical and Regulatory Affairs
E-mail: anickol@meridiandiagnostics.com

Date Summary Prepared: July 21, 1999

Name of Device: ImmunoCard STAT! STEC O157

Classification Name:
Antigens, All types, *Escherichia coli* [866.3255]; 83GMZ

Predicate Equivalent Device:
E. coli O157 Elisa Stool Assay

Description of Device:
Stool or culture material are prepared / diluted and added to the sample port of the device. The sample mobilizes gold particles, coated with monoclonal antibody specific for the O157 lipopolysacchride, and migrates along the membrane through the Test and Control zones. The test zone contains immobilized monoclodal antibody specific for an epitope common to shiga toxin producing *E. coli.* After ten minutes the Test and Control zones are observed for the presence of red/purple lines across the membrane surface. If a shiga toxin producing *E. coli* O157 is present in the sample, a complex is formed between the capture antibody, the shiga toxin producing *E. coli* O157, and the monoclonal antibody-gold conjugate which can be seen visually as a red/purple line in the Test zone. No red/purple line in the Test zone indicates a negative result. The Control line serves as a procedural control, to assure that the sample has migrated the appropriate distance along the membrane.

Intended Use:

The Immunocard STAT! STEC O157 is a rapid test for the detection of antigens from shiga toxin producing *E. coli* O157 as an aid in the diagnosis of *E. coli* O157:H7 infection. The test can be used to directly test stool specimens, or confirmatory stool cultures grown in MacConkey broth or sorbitol MacConkey (SMAC) plates.

Comparison with Predicate Device:

The following comparison of the use, technology, function and performance supports the Statement of Equivalence between the **ImmunoCard STAT! STEC O157** test and the *E. coli* ELISA Stool Assay. The differences in technology, specimens or assay procedure do not raise additional concerns regarding safety and effectiveness. The safety and effectiveness of both assays are both substantially equivalent when compared to culture.

Method	ImmunoCard STAT! STEC O157			*E. coli* O157 Elisa Stool Assay	
Intended Use	Detection of *E. coli O157* in patient stool			Detection of *E. coli* O157:H7 in patient stool	
Results	Qualitative			Qualitative	
Specimen Required	1. Stool 2. Stool in modified Cary-Blair Transport 3. MacConkey Broth 4. Non-Sorbitol fermenting colonies from a SMAC Plate			1. Stool 2. Preserved Stools (10% formalin)	
Technology	Sandwich Colloidal Gold Immunoassay			Sandwich Enzyme Immunoassay	
Level of Skill Required	Laboratory Technician			Laboratory Technician	
Function	1. Specimen is diluted and added to the sample application port. 2. After 10 minutes, results are read visually.			1. Specimen is diluted (1/3 for stool; none for formalin preserved) and 100µl are added to microwells. 2. Incubate 20 minutes at room temperature. 3. Wash wells 3 times. 4. Add 2 drops of Enzyme Conjugate to each well. 5. Incubate 10 minutes at room temperature. 6. Wash wells 3 times. 7. Add one drop each Substrates A and B. Mix and incubate 5 minutes at room temperature. 8. Add 2 drops Stop Solution, mix and read either visually or with a plate reader.	
Interpretation	Pos/Neg read visually			Pos/Neg read visually or spectrophotometrically	
Performance with	**Stool**	**Mac. Broth**	**SMAC Plate**	**Formalinized Stool**	**Stool**
Sensitivity	82%	100%	100%	93%	100%
Specificity	99%	100%	100%	99%	99%

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG -9 1999

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

Re: K990263
Trade Name: ImmunoCard STAT! STEC 0157 *E. coli*
Regulatory Class: I
Product Code: GMZ
Dated: July 21, 1999
Received: July 22, 1999

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

Meridian Diagnostics, Inc.
Cincinnati, OH 45244

Indications for Use Statement

510(k) Number (if known): **K990263**

Device Name: **ImmunoCard STAT! STEC O157**

Indications For Use:

The Immunocard STAT! STEC O157 is a rapid test for the detection of antigens from shiga toxin producing *E. coli* O157 as an aid in the diagnosis of *E. coli* O157:H7 infection. The test can be used to directly test stool specimens, or confirmatory stool cultures grown in MacConkey broth or sorbitol MacConkey (SMAC) plates.

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 K990263

Prescription Use X OR Over-The-Counter Use ____
(Per 21 CFR 801.109) (Optional Format 1-2-96)