K971585

APPENDIX A - 510(k) Summary

A. Identification Information

AUG 20 1997

1) **Submitter's Information:**

a) **Submitter's Name and Address:**

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

b) **Phone Number:** 1-800-543-1980

c) **Contact Person:** Allen D. Nickol, PhD
Director of Scientific and Regulatory Affairs

d) **Date Summary Prepared:** April 30, 1997

2) **Name of Device: ImmunoCard STAT Rotavirus.**

Classification Name: Enzyme Linked Immunoabsorbent Assay, Rotavirus.

3) **Predicate Equivalent Device:** Premier Rotaclone and Abbott Test Pack EIA's.

4) **Description of Device:** The **ImmunoCard STAT! Rotavirus** assay system is a membrane based immunogold assay for rotavirus. Each kit contains the following components:

a) ImmunoCard STAT! Rotavirus devices(30)
b) Positive Control (1.8ml)
c) Sample Diluent (10.5ml)
d) Transfer Pipets (30)

In brief, 1/15 diluted stool enters the sample application pad and migrates through the conjugate pad. Monoclonal antibody (conjugated to colloidal gold particles) contained in the pad is dissolved in the specimen and travels onto the nitrocellulose membrane. The nitrocellulose membrane contains two "capture" zones. The first holds polyclonal antibody to rotavirus, and the second has polyclonal anti-mouse IgG. The first zone serves as the test line, indicating the presence or absence of rotavirus. The second zone

acts as a procedural control and verifies that the sample has migrated sufficiently into the device to permit a valid test result to be read in the first (test) zone. The final absorbent pad acts as a reservoir and draws the sample through the test strip.

5) **Intended Use:** The **ImmunoCard STAT! Rotavirus** Immunoassay is a rapid in vitro qualitative procedure for the detection of rotavirus antigen in human stool. The test can be used to aid in the diagnosis of rotavirus associated gastroenteritis.

6) **Comparison with Predicate Devices:**

The following comparison of the use, technology, function and performance supports the Statement of Equivalence between the **ImmunoCard STAT! Rotavirus** test and enzyme immunoassay testing (Premier Rotaclone® and Abbott Test Pack®).

Method	**ImmunoCard STAT! Rotavirus**	Premier Rotaclone	Abbott Test Pack
Intended Use	Detection of rotavirus in patient stool		
Results	Qualitative		
Technology	Immunoassay		
Function			
Capture	Polyclonal Rabbit Ab	Monoclonal Ab	Polyclonal Guinea Pig Ab
Detection	Monoclonal Ab-Gold	Monoclonal Ab-HRP	Monoclonal Ab-Alk. Phos.
Color Change	White to Red / Purple	Clear to Blue	White to Purple
Chromogen	Colloidal Gold	TMB	Unknown
Procedure	1. 1/15 dilution 2. 150µl addition 3. Ten min RT incubation 4. Read visible results	1. 1/41 dilution 2. 100µl addition 3. 2 drops conjugate 4. mix 5. 60 min RT incubation 6. Decant & Wash 5X 7. 2 drops substrate 8. 2 drops chromogen 9. 10 min RT incubation 10. Read visible or 450nm Abs. results	1. 1/11 dilution and filtration 2. 3 drops conjugate 3. 5 min RT incubation 4. Pour through device and remove focuser 5. Wash (fill) 6. 3 drops substrate 7. 2 min RT incubation 8. Wash (fill) 9. Read visible results
Interpretation	Pos/Neg/Invalid	Pos/Neg	Pos/Neg/Invalid
Performance vs Electron Microscopy			
Sensitivity	93.1%	93.8%	93.8%
Specificity	95.8%	94.1%	90.8%
Correlation	94.4%	94.0%	92.4%
Performance vs Premier Rotaclone			
Sensitivity	97.7%	NA	98.4%
Specificity	100.0%	NA	95.0%
Correlation	98.8%	NA	96.8%

B. Additional Information/Non-clinical Test Results:

1) **Sensitivity Limits:** The sensitivity of the **ImmunoCard STAT! Rotavirus** is approximately 1.8-3.7 x 10^6 viral particles.

2) **Reproducibility:** Reproducibility of the **ImmunoCard STAT! Rotavirus** test was 100% on controls, negative and moderate positive stools, and 96% on low positive stools.

3) **Fresh versus Frozen Stools:** The data indicated rotavirus is stable in stool for at least three days when stored at 4°C or frozen at ≤-20°C.

4) **Cross-Reactivity:** Testing of the **ImmunoCard STAT! Rotavirus** with a panel of bacteria and viruses gave no false positive or false negative results.

5) **Interfering Substances:** Testing of the **ImmunoCard STAT! Rotavirus** with blood showed that high levels (≥33%) could affect flow, resulting in an occasional invalid test result. No effect from barium sulfate was observed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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

AUG 20 1997

Re: K971585
Trade Name: ImmunoCard® STAT! Rotavirus
Regulatory Class: I
Product Code: LIQ
Dated: June 30, 1997
Received: July 1, 1997

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 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

C. **Indications for Use Statement:**

510(k) Number (if known): NA

Device Name: ImmunoCard® STAT! Rotavirus

Indications For Use: For use to detect the presence of rotavirus in stool specimens from patients with loose stools, diarrhea, gastroenteritis, or suspected to be infected with rotavirus.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K971585

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