JAN 1 1 1999

ATTACHMENT 1

510(k) Summary Of Safety and Effectiveness Information

Trade or Proprietary Name: *Giardia/Cryptosporidium* Combo Rapid Assay

Common or Usual Name: Immunoassay for *Giardia* and *Cryptosporidium* Antigens

Manufacturer:
Genzyme Diagnostics
Medix Biotech subsidiary
1531 Industrial Road
San Carlos, CA 94070

Contact Person:
Barbara Pizza, Manager Regulatory Affairs, (617) 252-7953
Genzyme Diagnostics
One Kendall Square, Building 200
Cambridge, MA 02139-1562

The use of the Genzyme *Contrast® Giardia/Cryptosporidium* Combo Rapid Assay in the clinical laboratory setting is substantially equivalent to a currently marketed method for *Giardia* and *Cryptosporidium* for the detection of *Giardia* and *Cryptosporidium* antigen in aqueous fecal specimens.

PERFORMANCE STUDIES:

Comparative Performance Studies

A Comparative performance study was conducted using the Genzyme *Giardia/Cryptosporidium* Assay, a Reference method (microscopic examination) and predicate method (Alexon ProSpecT). The summary of the sensitivity and specificity are provided below.

	Sensitivity	**Specificity**
Retrospective Analysis Genzyme vs Microscopic examination		
Giardia	33/33 = 100%	109/109 = 100%
Cryptosporidium	36/37 = 97.3%	105/105 = 100%
Prospective Analysis Genzyme vs Microscopic examination		
Giardia	50/50 = 100%	448/452 = 99.1%
Cryptosporidium	73/73 = 100%	427/429 = 99.5%
Retrospective Analysis Genzyme vs Rapid EIA		**Relative Agreement**
Giardia		138/142 = 97.2%
Cryptosporidium		142/142 = 100%

The Genzyme method yielded acceptable relative agreement with the predicate method.

Agreement

Both within-run and between-run studies were performed using *Giardia* and *Cryptosporidium* positive and negative stool specimens. Five replicates of each specimen stool pool (*Giardia* positive, *Cryptosporidium* positive and *Giardia/Cryptosporidium* negative) was tested five times in one batch using the Contrast *Giardia/Cryptosporidium* Combo Rapid Assay over five days. The Agreement was calculated for each stool specimen. Target specifications for within and between-run precision were 100% agreement.

Conclusion

Based on the results of the performance studies described above, the Genzyme *Contrast Giardia/ Cryptosporidium* Combo Rapid Assay is substantially equivalent in performance to the reference method (Standard microscopic examination) and to the predicate (Alexon ProSpecT) a legally marketed method for the detection of *Giardia* and *Cryptosporidium* antigen in aqueous fecal specimens.

In lieu of a 510(k) statement under 513(i) of the Act, this information is provided as a 510(k) summary for disclosure to any other persons/companies without the specific written authorization from Genzyme Corporation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 11 1999

Barbara Pizza
Manager, Regulatory Affairs
Genzyme Diagnostics
One Kendall Square
Cambridge, MA 02139-1562

Re: K983399
Trade Name: Contrast® *Giardia/Cryptosporidium* Combo Rapid Assay
Regulatory Class: II
Product Code: MHI
Dated: December 23, 1998
Received: December 24, 1998

Dear Ms. Pizza:

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

510(k) Number (if known): K983399

Device Name:4 *Contrast® Giardia/Cryptosporidium* Combo Rapid Assay

Indications For Use:

This is an immunochromatographic assay for the simultaneous qualitative detection and distinguishing of *Giardia* and *Cryptosporidium* specific antigens in aqueous extracts of fecal specimens.

It is intended for professional laboratory use.

For In Vitro Diagnostic Use.

Woody Dutour
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K983399

PRESCRIPTION USE X