3/15/99

K983119

APPENDIX 4

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92.

The assigned 510(K) number is:_____.

Name of In-Vitro Diagnostic Device:	Entero-Test®HP
Common Name:	Specimen Collection Device
Classification Name:	83LIO
Predicate Devices:	Entero-Test®- (preamendments device) Entero-Test® Pediatric- (preamendments device)
Device Description:	The Entero-Test® HP is collection device encased in a gelatin capsule. It can be used to collect fluids/mucous in the upper gastrointestinal tract of adults. A pH stick and a color chart are included in each package for the purpose of identifying the pH of the fluids/mucous.
Intended Use:	The Entero-Test® HP is an in-vitro diagnostic device to be used for the collection of fluid/mucous containing *Helicobacter pylori* from the upper gastrointestinal tract of adults. The device consists of a nylon thread, 90cm in length, coiled inside a #00 gelatin pharmaceutical capsule.
Device/Predicate Device Characteristics	The Entero-Test® HP retains the following characteristics of the predicate device: ❖ Both devices are used for the collection of fluids/mucous ❖ Both utilize the same operating principle

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- Both incorporate the same device design
- Both have the same shelf life
- Both are packaged using same materials and process
- Both are sterilized utilizing the same validated method
- Both utilize exactly the same materials
- Both retain the same technological characteristics
- Both retain the same technological features
- Both devices have the same risk assessments

Performance Data:

The clinical tests conducted for the Entero-Test® HP show that the In Vitro Diagnostic device is effective in collecting upper gastrointestinal tract fluid/mucous that contain *Helicobacter pylori.*

As Biopsy is considered the "gold standard" for determining the presence of *Helicobacter pylori* in a sample specimen, the performance of the Entero-Test® HP in successfully collecting fluids/mucous containing *H. pylori* was directly compared to the Biopsy results.

The comparative results of the studies in the U.S. and China do not show a significant difference (74% vs. 80% recovery). Both study sites indicate that the Entero-Test® HP is effective in collecting fluids/mucous containing *Helicobacter pylori* from the upper gastrointestinal tract of adults in excess of seventy percent (70%) when compared to Biopsy test results.

In the studies described above, it was noted that the pH of retrieved stomach contents may affect specimen results, and is therefore so stated in the limitations under the Instructions for Use.

No adverse reactions or serious injuries were reported from both sites.

Conclusions:

Entero-Test® HP is a device that can be used to collect fluid/mucous containing *Helicobacter pylori* from the upper gastrointestinal tract of adults.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 15 1999

Leonard O. Ross
Vice President
HDC Corporation
2109 O'Toole Avenue
San Jose, CA 95131-1388

Re: K983119
Trade Name: Entero-Test® HP
Regulatory Class: I
Product Code: LIO
Dated: December 29, 1998
Received: January 4, 1999

Dear Mr. Ross:

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

APPENDIX 6

Indications for Use Statement

510(k) Number K983119

Device Name Entero-Test® HP

Indications for Use The Entero-Test® HP is an in-vitro diagnostic device indicated for the collection of fluids/mucous containing *Helicobacter pylori* from the upper gastrointestinal tract of adults. The device consists of a nylon thread, 90cm in length, coiled inside a #00 gelatin pharmaceutical capsule.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Woody Dubois
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K983119

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