

510(k) Summary

MAR - 3 1998

K973523

Introduction According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1) Submitter name, address, contact Owner/Operator
Cortecs Diagnostics Limited
Newtech Square
Deeside Industrial Park
Deeside, Flintshire CH5 2NT
Wales

USA Regulatory Representative/Distributor
Boehringer Mannheim Corporation
9115 Hague Rd.
Indianapolis, IN 46250
(317) 845-2000

Contact Person: Mike Flis

Date Prepared: September 15, 1997

2) Device name Proprietary name: AccuStat™ H. pylori One Step Test
Common name: Laboratory Test for the Detection of Antibodies to
Helicobacter pylori
Classification name: Campylobacter fetus serological reagents

3) Predicate device The Cortecs Diagnostics Limited AccuStat H. pylori One Step Test is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed Cortecs Helisal Rapid Blood Test (510(k) file #k953686). The AccuStat H. pylori One Step Test is also substantially equivalent to Smith Kline FlexSure HP and Quidel QuickVue One-Step H. Pylori tests. The latter two tests have been determined by the Center for Disease Control and Prevention (CDC) as being eligible for a CLIA waiver due to the simple methodologies employed.

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510(k) Summary, Continued

4) Device Description Visually read, single use test cassette.

5) Intended use The AccuStat™ *H. pylori* One Step test is a qualitative immunochemical membrane assay for the detection of antibodies to *Helicobacter pylori* (*H. pylori*) in whole blood and serum by visual interpretation. The test is for use as an aid in the diagnosis of *H. pylori* infection in symptomatic patients.

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510(k) Summary, Continued

| Feature | AccuStat H. pylori One Step Test (new device) | Cortecs Helisal Rapid Blood Test (Primary Predicate) | Smith Kline FlexSure HP Test (Secondary Predicate) | Quidel QuickVue One-Step H. pylori Test (Secondary Predicate) |
|-------------------------------|--|--|--|--|
| Detects | Human antibody to <i>Helicobacter pylori</i> | Human IgG antibody to <i>Helicobacter pylori</i> | Human IgG antibody to <i>Helicobacter pylori</i> | Human IgG antibody to <i>Helicobacter pylori</i> |
| Methodology | Immunochromatography (visually interpreted) | Immunochromatography (visually interpreted) | Immunochromatography (visually interpreted) | Immunochromatography (visually interpreted) |
| Qualitative Test? | Yes | Yes | Yes | Yes |
| Test Components | Single use test cassette | Single use test card and buffer | Single use test card and buffer | Single use test cassette |
| Minimum test sample | 1-2 drops of whole blood or serum (50 µL) | 20µL whole blood | 80µL whole blood or serum | 140 µL whole blood or serum |
| Procedural Steps | <ol style="list-style-type: none"> 1. Add sample 2. Wait 3. Read result | <ol style="list-style-type: none"> 1. Fill capillary tube 2. Drop tube in buffer 3. Mix 4. Add sample to test card 5. Wait 6. Wipe card 7. Add reagent 8. Wait 9. Read result | <ol style="list-style-type: none"> 1. Add buffer 2. Add sample 3. Wait 4. Close test card 5. Wait 6. Read result | <ol style="list-style-type: none"> 1. Add sample 2. Wait 3. Read result |
| Total test time | ≤ 5 minutes | 5-10 minutes | 6-7 minutes | 10 minutes |
| Quality control | Internal procedural control | Internal procedural control | Internal procedural control | Internal procedural control |
| Storage Recommendation | Room temperature | Room temperature | Refrigerated | Room temperature |



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Mike Flis
Regulatory Affairs Consultant
Boehringer Mannheim Corporation
9115 Hague Road
Indianapolis, IN 46250

MAR - 3 1998

Re: K973523
Trade Name: AccuStat H. pylori One Step Test
Regulatory Class: I
Product Code: LYR
Dated: December 15, 1997
Received: December 16, 1997

Dear Mr. Flis:

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.

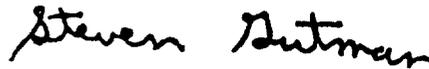
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

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

Enclosure

Indications for Use Statement

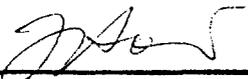
510(k) Number (if known): K 973523
Device Name: AccuStat H. pylori One Step Test

Indications for Use:

The AccuStat™ H. pylori One Step test is a qualitative immunochemical membrane assay for the detection of antibodies to *Helicobacter pylori* (*H. pylori*) in whole blood and serum by visual interpretation. The test is for use as an aid in the diagnosis of *H. pylori* infection in symptomatic patients.

(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 K97.3523

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

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