510(k) Summary

Safety and Effectiveness as Required by 21 CFR 807.92

Manufacture and submitter	**Name:**	Alfa Scientific Designs, Inc.
	Address:	12330 Stowe Drive Poway, CA 92064 Telephone: (858) 513-3888 x 308 Fax: (858) 513-8388
	Contact Person:	Naishu Wang, MD, Ph.D.
	E-mail:	wnss@alfascientific.com
Device Name	**Trade Name:** *Instant-View® H. Pylori Rapid Test-Serum (Cassette)* *Instant-View® H. Pylori Rapid Test-Serum (Dip Strip)* *Instant-View® H. Pylori Rapid Test-Whole Blood/Serum (Cassette)* **Common Name:** Immunoassay, *H. Pylori* Test **Classification:** Campylobacter fetus serological reagents (21 CFR § 866.3110) Class I (reserved)	
Date of Summary Preparation	June 9, 2003	
Predicate Device	SureStep™ *H. Pylori* Test, Applied Biotech, Inc. **K984393** (Serum and Plasma), **K990892** (Whole Blood)	
Device Description	A one-step lateral flow chromatographic immunoassay. The test strip in the device consists of 1) a burgundy-colored conjugate pad containing colloidal gold coupled with *H. Pylori* antigens, and 2) nitrocellulose membrane containing a test line (T line) and a control line (C line). The T line is coated with *H. Pylori* antigens, and the C line is coated with goat anti-*H. Pylori* antibodies.	
Summary of the Similarity to the Predicate Device	• Both are one-step lateral-flow chromatographic immunoassays. • Both are intended to provide qualitative detection of IgG antibodies specific to *H. Pylori*. • Both are in vitro diagnostic devices. • Both have a built-in quality control feature, C line, to indicate that an adequate volume of sample is applied and the device performs properly	

Intended Use	The Instant-View® *H. Pylori* Rapid Test is a rapid lateral flow, qualitative immunoassay. It is intended for use at point of care facilities to detect the presence of IgG antibodies specific to *Helicobacter pylori* (*H. pylori*) in human blood or serum. It provides an aid in the diagnosis of infection by *H. pylori*.
Sensitivity and specificity study	The sensitivity and specificity of the device was evaluated with 296 clinically confirmed serum specimens, 144 positive and 152 negative. The results demonstrated that the Instant-View® *H. Pylori* Rapid Test has a sensitivity of 95%(137/144) and a specificity of 93%(141/152). The overall accuracy of this device is 94% (278/296).
Reproducibility study	Reproducibility studies were performed on 20 negative, 20 borderline positive and 20 positive serum specimens at three physician's office laboratories (POL). Each specimen was run in triplicates for three days at each POL. All the intra-assay agreements were 100% except one, which was 99.4%. The inter-assay agreement was 100% at two POLs and 99.8% at one. The inter-site agreement was 99.9%.
Interference and cross-reactivity study	No cross-reaction was observed with the closely related microorganisms, such as Campylobacter fetus, Campylobacter jejunii, C. coli, or E. coli at a high concentration. No cross-reaction or interference was observed with endogenous substances including common serum components, such as lipids, hemoglobin, bilirubin, and other common biological or chemical analytes at a high concentration evaluated.
Formats of the device	The proposed device has two formats: Serum Test and Whole Blood/Serum Test, and the Serum Test has two sub-formats: Cassette and Dip-Strip. A cassette is a device that assembles a dip-strip in a plastic housing. The studies demonstrate all the formats are equivalent.
Conclusion	The results of specificity, sensitivity, reproducibility, cross reactivity, and interference studies demonstrate that the *Instant-View*® *H. Pylori Rapid Test* is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 1 0 2003

Naishu Wang, M.D., Ph.D.
President
Alfa Scientific Designs, Inc.
12330 Stowe Drive
Poway, CA 92064

Re: k024360
Trade/Device Name: *Instant-View*® H. pylori Rapid Test-Serum (Cassette)
Instant-View® H. pylori Rapid Test-Serum (Dip Strip)
Instant-View® H. pylori Rapid Test-Whole Blood/Serum (Cassette)
Regulation Number: 21 CFR 866.3110
Regulation Name: Campylobacter Fetus Serological Reagents
Regulatory Class: Class I
Product Code: LYR
Dated: May 23, 2003
Received: June 2, 2003

Dear Dr. Wang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(K) NUMBER (IF KNOWN): k024360

DEVICE NAME: *Instant-View*® H. Pylori Rapid Test-Serum (Cassette)
Instant-View® H. Pylori Rapid Test-Serum (Dip Strip)
Instant-View® H. Pylori Rapid Test-Whole Blood/Serum (Cassette)

INDICATIONS FOR USE:

The Instant-View® H. Pylori Rapid Test is a rapid lateral flow, qualitative immunoassay. It is intended for use at point of care facilities to detect the presence of IgG antibodies specific to *Helicobacter pylori* (*H. pylori*) in human blood or serum. It provides an aid in the diagnosis of infection by *H. pylori*. This test has been evaluated for use with serum specimens of adults, 19 years and older.

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K024360

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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